



**A prospective, controlled study of assertive and timely reperfusion for patients with ST-segment elevation myocardial infarction in Tamil Nadu- The TN-STEMI Programme**

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2013-003850
Article Type:	Protocol
Date Submitted by the Author:	19-Aug-2013
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<b>Primary Subject Heading</b>:	Cardiovascular medicine
Secondary Subject Heading:	Health services research, Epidemiology, Global health, Public health, Medical education and training
Keywords:	Cardiac Epidemiology < CARDIOLOGY, Coronary heart disease < CARDIOLOGY, Myocardial infarction < CARDIOLOGY, Ischaemic heart disease < CARDIOLOGY

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6 **A prospective, controlled study of assertive and timely reperfusion for**  
7 **patients with ST-segment elevation myocardial infarction in Tamil Nadu**  
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11 **The TN-STEMI Programme**  
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19 For TN-STEMI Programme Investigators  
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23  
24 **Abstract**  
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26  
27 **Introduction:** Over the last two decades, India has witnessed a staggering increase in the  
28 incidence and mortality of ST-elevation myocardial infarction (STEMI). Indians have higher  
29 rates of STEMI and younger populations that suffer from it when compared with developed  
30 countries. Yet recommended reperfusion therapy with fibrinolysis and percutaneous coronary  
31 intervention (PCI) are available to only a minority of patients. This gap in care is a result of  
32 financial barriers, limited healthcare infrastructure, and poor knowledge and accessibility of  
33 acute medical services for a majority of its population.  
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37 **Methods and analysis:** Encouraged by the results of the previously conducted 'Kovai-Erode  
38 STEMI pilot study,' we designed the current prospective study which will study whether or  
39 not optimal and timely reperfusion therapy can be delivered to high-risk patients in India.  
40 Novel aspects of this study involve: creating integrated networks of facilities across the state  
41 of Tamilnadu; leveraging newly-developed ambulance and emergency medical services;  
42 incorporating recent state insurance schemes for vulnerable populations to broaden access;  
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3 and combining innovative, “state-of-the-art” information technology platforms with existing  
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5 hospital infrastructure.  
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8 **Ethics:** This study will be conducted in accordance with the ethical principles that have their  
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10 origin in the current declaration of Helsinki and ‘ethical guidelines for biomedical research  
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12 on human participants’ as laid down by the Indian Council for Medical Research. All  
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14 participating hospitals will still obtain local ethics committee approval of the study protocol  
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16 and written informed consent will be obtained from all participants.  
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20 **Dissemination and results:** Our findings will be reported through scientific publications,  
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22 research conferences, and public policy venues aimed at state and local governments in India.  
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24 If successful this model can be extended to other areas of India as well as serve as a model of  
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26 STEMI systems of care for low-and-middle income countries across the world.  
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30 **Registration:** Trial is registered with Clinical trial registry of India, No:  
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## Introduction

In the last 40 years cardiovascular disease in India has quadrupled, and by 2020, estimates suggest that almost 60% of patients with cardiovascular disease worldwide will be Indian (1). One of the most ominous manifestations of cardiovascular disease is ST elevation myocardial infarction (STEMI), which carries a grave prognosis if not treated promptly using reperfusion therapy to re-establish flow in the occluded coronary artery (2). Unfortunately, national registry data from 89 cities suggest that Indian patients with STEMI frequently fail to receive adequate reperfusion therapy and to a greater extent than comparable patients in developed countries (3). For example, reperfusion therapy with fibrinolysis is received by less than 60% of Indian patients with STEMI and those that undergo it often do so after great delays. Furthermore, few patients go on to early invasive evaluations and less than 10% receive percutaneous coronary intervention (PCI) during their hospitalization despite growing support for this type of pharmacoinvasive approach. Improving access to these critical treatments is a key opportunity to improve STEMI care that has large implication for India as the epidemic of cardiovascular diseases continues to grow.

However, the challenges to improving STEMI care in India are formidable and include non-clinical factors, such as financial barriers, limited healthcare infrastructure, and poor accessibility of acute medical services for a majority of its population. We therefore previously designed the Kovai Erode Pilot STEMI Study to assess the feasibility of developing a treatment model for STEMI in India based on analogous “systems of care” developed in North America and Europe (4). This study was done in the rural district of Erode, located in the Northern part of Tamilnadu. As a proof-of-concept study it demonstrated that by linking several smaller, peripheral “spoke” hospitals with a centrally-located, PCI-capable “hub” hospital, the use and timelines of reperfusion therapy could be improved. Encouraged by these results, we now propose a broader ‘hub and spoke’ model in

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3 other areas of Tamilnadu: the TN-STEMI programme. The purpose of this paper is to  
4  
5 describe the framework and methods associated with this programme – the first-ever, multi-  
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7 centre study that aims to improve delivery of reperfusion therapy in India. If successful, this  
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9 programme can be extended to other areas of the country and serve as a model of STEMI  
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11 systems of care for low-and-middle income countries.  
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## 13 14 15 **Methods & Analysis**

### 16 17 18 *Study design and objectives*

19  
20 The TN- STEMI programme is a prospective, multi-centre study that has been planned as a  
21  
22 community-based treatment programme for improving use and timeliness of reperfusion  
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24 therapy in patients diagnosed with STEMI as confirmed by an ECG. It involves a stepwise  
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26 approach that facilitates rapid and definitive restoration of coronary blood flow using a  
27  
28 combination of pharmacological and mechanical reperfusion therapies based on the  
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30 presentation of the patient. This programme will use a ‘hub-and-spoke’ model that relies on  
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32 an integrated healthcare network based on clusters of primary-care health clinics and small  
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34 hospitals built around 4 large tertiary-care facilities that are capable of providing advanced  
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36 cardiovascular services, including PCI and cardiac surgery. The primary objectives of the  
37  
38 TN-STEMI programme is to use organized systems of care to: (1) improve the use of  
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40 reperfusion therapy and reduce the time from first medical contact to device or drug in  
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42 STEMI patients; and (2) increase rates of early invasive risk stratification in eligible patients.  
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48 We plan to measure our ability to achieve this overall objective through explicit  
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50 measurement of changes in processes of care before and after introduction of the TN STEMI  
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52 programme. Secondary (and implicit) objectives include:  
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- 54 • Integrating care between emergency medical services (EMS) and acute-care clinics  
55 and hospitals at the community level in India, especially in rural areas.  
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- Providing a pragmatic model to understand the challenges associated with developing a national STEMI programme in India.
- To increase public awareness of appropriate STEMI care in India

### *Study population, facilities and enrolment period*

The TN-STEMI programme incorporates an inclusive, “all-comers” study design. Consecutive patients aged 20 years or older with symptoms or signs consistent with acute coronary syndromes and ECG confirmation of STEMI will be enrolled. For entry into the study, an ECG must have evidence of myocardial injury showing  $\geq 1$ -mm ST-segment elevation in at least 2 anatomically contiguous limb leads (aVL to III, including -aVR),  $\geq 1$ -mm ST-segment elevation in a precordial lead V4 through V6,  $\geq 2$ -mm ST-segment elevation in V1 through V3 or a new left bundle branch block.

Both “hub” hospitals and “spoke” hospitals are included in each of the 4 clusters. The hub hospitals are 4 large tertiary-care hospitals with the capability for emergency cardiac catheterization and PCI (Table 1). Participating hub hospitals are divided into class A or B facilities depending upon the availability of around-the-clock PCI at the hospital. The spoke hospitals have been selected based on their proximity to the hub hospitals. Spoke hospitals situated within 30 minutes of a hub hospital have been classified as class C while those beyond 30 minutes were class D hospitals. All participating units had to commit to complying with the study protocol and were required to be within the catchment area for available emergency ambulance services. Details of the hub-and-spoke model are discussed below.

Baseline data on management and outcomes of STEMI patients will be collected for 3 months at all the participating hospitals during an enrolment period that started in the fall of 2012. The enrolment period will be “rolling” for each of the hospitals and followed by 9

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3 months of post-implementation data collection on STEMI patients after execution of the TN-  
4 STEMI programme. Outcomes that we will be evaluating are discussed in detail below and  
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7 include data on processes of care that will be available during the hospitalization and follow  
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10 up data for one year from the index event; the 1 year follow up will either be a hospital visit,  
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12 if it is the routine practice at the local site or a telephonic follow up if hospital visit is not  
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14 required by the treating hospital. Estimated loss to follow up is 20%.

### 15 16 17 18 19 **TN-STEMI programme: the hub and spoke model**

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21 We have organized the network of hospitals within the TN-STEMI programme using a “hub-  
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23 and-spoke” model that recognizes four classes of healthcare facilities that care for STEMI  
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25 patients in India:  
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28 • **Class A Hospital** - Class A hospitals are PCI-capable hospitals with healthcare teams  
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30 available 24/7 for managing STEMI and its complications. Patients admitted to these  
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32 hospitals typically undergo primary PCI with an aim of door-to-balloon time less than  
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34 90 minutes.
- 35  
36 • **Class B Hospital** - These are PCI-capable hospitals, but primary PCI cannot be  
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38 performed outside of working hours. Patients admitted to a class B hospital outside of  
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40 working hours are typically are treated with fibrinolysis with a goal of door-to-needle  
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42 time less than 30 minutes. Patients would be taken for catheterization within the next  
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44 3 to 24 hours, in the same hospital, and undergo PCI, if indicated. Patients at this class  
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46 of hospitals may undergo primary PCI (like a Class A Hospital) if the patient arrives  
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48 during working hours.
- 49  
50 • **Class C Hospital** – These are healthcare facilities and hospital with the capability to  
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52 perform and transmit ECGs *and* that are located within 30 minutes of a Class A or  
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54 Class B hospital. All Class C hospitals would constitute the spokes of the Class A/B  
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3 hospitals. Upon confirmation of STEMI, the class C hospitals will activate GVK-  
4 EMRI ambulance, transmit the ECG and transfer the patient to a Class A/B hospital.  
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6 This process of transfer should ideally take less than 60 minutes.  
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10 • **Class D Hospital** - This class of healthcare facilities and hospitals have the capability  
11 to perform and transmit ECGs *but* are located beyond 30 minutes of PCI-capable  
12 hospital. All of these are capable of providing fibrinolysis. All Class D hospitals  
13 would constitute the spokes of Class A/B hospitals. Patients arriving at a Class D  
14 hospital are treated with fibrinolysis after confirmation of STEMI as per routine  
15 hospital practice. After informing the receiving hospital that is linked to it, transfer of  
16 the patient via GVK-EMRI ambulance for urgent catheterization and, if indicated  
17 PCI, within the next 3 to 24 hours.  
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28 Each Class A/B hospital will be linked to approximately 3 to 15 referring Class C/D  
29 hospitals. A full list of the participating hospitals organized by their classes is presented in  
30 Table 1. Figure 1 shows the “hub-and-spoke” model; Figure 2 shows a geographical map of  
31 Tamilnadu State showing locations of clusters of “hub-and-spoke” hospitals in the TN-  
32 STEMI programme.  
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### 39 **Key partners in TN-STEMI programme**

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42 The TN-STEMI programme involves 3 key partners from both the public and private sectors:  
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- 45 1. **Government of Tamilnadu – Chief Minister’s Health Insurance Scheme.** A  
46 recent and important development that is relevant to the TN-STEMI programme in  
47 India has been the establishment and growth of government-sponsored social  
48 insurance coverage for healthcare among those below the poverty line. This has been  
49 a state-based development, including the Chief Minister’s Health Insurance Scheme  
50 in Tamilnadu. All the hub and spoke hospitals in each cluster will be covered by this  
51 programme. This requirement will ensure that patients from all social classes can  
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3 receive timely and suitable treatment for STEMI with no out-of-pocket expenses  
4 incurred for their hospitalization. The Chief Minister's Health Insurance scheme is  
5 currently operated by 3 insurance companies: Tiruvellore Thattai Krishnamachari  
6 TTK Healthcare, MediAssist and MD India Third Party Administrator.  
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12 **2. EMRI Ambulance.** Gunapati Venkata Krishna Emergency Management and  
13 Research Institute (GVK-EMRI) operates as a public-private-partnership and is  
14 recognized as a not-for-profit entity. It is an organization that has pioneered the  
15 development of emergency medical services (EMS) in India, including training  
16 paramedics, technicians, nurses and physicians in emergency care. GVK-EMRI  
17 ambulance services may be activated by a patient with chest pain or a healthcare  
18 facility using the "Call 108" system. Units within this EMS are capable of acquiring  
19 ECGs, transmitting ECGs to an 'on call cardiologist' for STEMI confirmation,  
20 locating the nearest PCI-capable hospital using GPS provided by a coordinating  
21 centre, and transferring the patient to the closest hospital. GVK-EMRI ambulances  
22 will also transport patients from the spoke hospital to the hub hospitals after initial  
23 evaluation and possible treatment.  
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39 **3. STEMI-India.** STEMI-India is a not-for-profit entity dedicated to STEMI care in  
40 India led by physicians from across the country. The purpose of this organization is to  
41 review and disseminate the latest information from across the world on STEMI  
42 management to providers involved in STEMI care in India; to help organize and train  
43 STEMI teams in hospitals; and to develop STEMI systems of care appropriate to the  
44 context of healthcare systems' needs and resources in India. Other goals include:  
45 facilitating and contributing to national STEMI guidelines within India and improving  
46 public education to reduce delays in accessing care. The organization's role in the  
47 TN-STEMI programme has been to provide expertise in the development and  
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oversight of the study protocol to meet standards of care within India for STEMI patients.

In addition to the 3 key partners above, we have partnered with 2 technology firms, Aosta and Maestro technologies, to coordinate the development of novel software and hardware (described below). Finally, Lotus Clinical Research Academy Pvt. Ltd has been involved with the clinical administration of the trial. The TN-STEMI programme is supported by an independent grant from the Indian Council for Medical Research (ICMR).

### **STEMI Technology**

A novel aspect of the TN-STEMI programme is the implementation of new hardware and software components to optimize the performance and transmission of ECGs and other clinical information across the network of hospitals in India by paramedics, nurses and physicians. The hardware will comprise of the 'STEMI Kit' (Figure 3) that includes:

1. ***ECG recording device*** - ECG devices will record the patient's ECG which would then be transmitted by paramedics to a hand held device of the STEMI coordinator in a hub hospital.
2. ***Vital signs monitoring device*** - This device will record the patient's vital signs and hemodynamic status, including pulse oxygen saturation, non-invasive blood pressure, heart rate and rhythm strip. This will also permit the transmission of key information by paramedics to STEMI coordinators at hub hospitals.
3. ***Display and transmitting device*** - Each STEMI coordinator will have a hand held device which collects and transmits data when required with sufficient battery support. This will allow for communication between STEMI coordinators and on-call cardiologists at the Class A/B hospitals.

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3 Coordination of the hardware units by paramedics, STEMI coordinators and on-call  
4 cardiologists will be performed through unique software applications that are specifically  
5 designed for the TN-STEMI programme to be used across a universal platform for multiple  
6 devices. These are summarized in the Appendix.  
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11 The paramedic and STEMI coordinators will capture the patient demographic details  
12 along with a checklist for eligibility for fibronolytic therapy. This information along with the  
13 ECG will be transmitted to the on-call cardiologist in that cluster to diagnose STEMI and  
14 decide on initial treatment. The on-call cardiologist receives an alert once these data are  
15 obtained. She (or he) can then go over the patient records, ECG and confirm STEMI. This in  
16 turn alerts the paramedic to transport the patient to the destination based on global positioning  
17 system (GPS) navigation. A dedicated server will be available round the clock to route all  
18 information from one hand held device to the other in ambulance or hospital. Data are  
19 simultaneously stored on the server along with the ECG snapshot which can be accessed by  
20 teams at the receiving hospital.  
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### 34 35 **Treatment Protocols**

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37 There will be two strategies to manage STEMI patients and both are adapted from current  
38 American College of Cardiology/American Heart Association and European Society of  
39 Cardiology guidelines for the context of the healthcare system of Tamilnadu (5,6). Overall,  
40 these guidelines intend to minimize the total ischemic time (7).  
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47 1. *Primary and Rescue PCI*: All patients with STEMI presenting to a Class A hospital,  
48 Class B hospital during working hours, and Class C hospital with an estimated  
49 transportation time of less than 60 minutes will undergo primary PCI. The aim is to  
50 achieve a door-to-balloon time of less than 90 minutes and a first medical contact to  
51 balloon time of less than 120 minutes. Inter-hospital transfer of the patient from a  
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3 spoke to a hub hospital is expedited from Class D hospitals if: (1) fibrinolysis is  
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5 contraindicated; or (2) unsuccessful fibrinolysis is clinically suspected with failed  
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7 reperfusion (i.e., rescue PCI).  
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- 10 2. *Pharmacoinvasive Strategy*: All patients with STEMI presenting to a Class B hospital  
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12 outside of working hours or Class D hospital with anticipated long transportation  
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14 times, unless contraindicated, will receive fibrinolysis as per routine hospital practice  
15  
16 with goal of door-to-needle time less than 30 minutes. Patients will then be transferred  
17  
18 for an early invasive strategy with coronary angiography and PCI, if indicated, within  
19  
20 3 to 24 hours of receiving fibrinolytic therapy.  
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23 All other medical therapy will be at the discretion of the treating physician and the healthcare  
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25 team. However, the use of immediate dual antiplatelet therapy and anticoagulation with  
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27 heparin or equivalent drugs is encouraged. Other therapies, such as morphine, nitroglycerin,  
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29 beta-blockers and calcium-channel blockerse, are not standardized.  
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32 All participating units will have a single protocol in place for reperfusion therapy and  
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34 cardiac catheterization laboratory activation. Prior to the implementation phase of the TN-  
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36 STEMI programme, hospitals will adopt a specific strategy for reperfusion therapy based on  
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38 distance, logistics, resources and equipment availability. STEMI kits consisting of  
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40 ‘Operations Manual and Guidelines for Management at First Medical Contact’ will be  
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42 circulated. These operations manual detail the interventional strategy at each point of care:  
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44 the ambulance, the emergency department, inter-hospital transfer, and the role of the  
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46 hospitals. A STEMI coordinator responsible for accurate management of the project will be  
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48 identified at each point of system care.  
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52 Patients with chest pain who call ‘108’ will enter the system outside of the hospitals.  
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54 These patients will be picked up by the EMRI ambulance, will have a preliminary ECG  
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56 performed in the out-of-hospital setting, vital signs recorded and transmitted to the on- call  
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3 cardiologist and STEMI coordinator. Once STEMI is confirmed by the on-call cardiologist,  
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5 the ambulance will use GPS to locate the closest hospital in the cluster and re-route the  
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7 patient there for appropriate treatment. Even before the patient reaches the hospital, the  
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9 STEMI coordinator organizes the cardiac catheterization laboratory (if transport is to hub  
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11 hospital) or coronary care unit for fibrinolysis (if transportation is to spoke hospital) based on  
12  
13 the proximity of the patient to the nearest hospital. In the overall protocol for the TN-STEMI  
14  
15 programme, any patient with cardiogenic shock will be taken directly to a Class A/B hospital  
16  
17 for primary PCI, bypassing a referring hospital even if it is the closest hospital.  
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### 20 21 *Primary and Secondary Outcomes*

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24 Our primary outcomes will be based on care provided during the hospitalization and process  
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26 measures associated with the use of and time to reperfusion therapy. Secondary outcomes  
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28 will be clinical events that occur during the hospitalization and follow-up, although we  
29  
30 recognize that we will be underpowered to detect differences in these events. These are  
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32 detailed below.  
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### 35 36 *Primary Outcomes*

- 37  
38 • Use of reperfusion therapy with either fibrinolytic therapy or primary PCI
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40 • Use of timely reperfusion defined as door-to-balloon time  $\leq 90$  minutes or door-to-  
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42 needle  $\leq 30$  minutes in patients with STEMI treated with primary PCI and fibrinolytic  
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44 therapy, respectively
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46 • Use of early invasive risk stratification with coronary angiography and PCI in patients  
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48 treated with fibrinolytic therapy
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### *Secondary Outcomes*

- Use of rescue PCI in patients with failed fibrinolysis.
- Composite of the following in-hospital outcomes: mortality, recurrent infarction/ischemia, stroke, major and minor bleeds.
- Composite of the following outcomes at 1-year: all-cause mortality, cardiac mortality, stroke, recurrent infarction/ischemia, major and minor bleeds.
- Use of evidence-based therapies – aspirin, beta-blocker and statin – on admission, at discharge and during follow-up

### *Statistical considerations*

Data from all centres will be combined for analysis. Data will be collected and processed into a quality assured database. Descriptive data will be provided in statistical summary tables and listings. Graphical presentations may also be presented where necessary. Continuous variables will be summarized using descriptive statistics such as mean, standard deviation, coefficient of variation (%), median, minimum and maximum; and the same will be reported. For categorical data, the number and percentage of participants in each category will be reported, along with 95% two-sided confidence intervals (95% CI) where appropriate. Comparison between patients treated during the enrolment period and post-implementation periods based on the study outcomes will be tested using applicable test of hypothesis such as t-test, chi-square test or non parametric tests.

Eligible patients from the study with reference to the definition of control population and intervention population will be used for statistical comparison. Control population is defined as population included prior to implementation of TN-STEMI programme into a cluster that will provide baseline data for evaluation of operational parameters and outcomes before and after the intervention (i.e., the enrolment period). Intervention population as per

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2  
3 protocol is defined as patients presenting to hub and spoke centres after initiation of a cluster  
4 into TN-STEMI programme (i.e., the post-implementation period). This will also include  
5 patients who were transferred and completed the study protocol, patients who were  
6 transferred and did not complete the study prior to intervention and post intervention.  
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11 No formal sample size estimation has been done since this is a real-world  
12 implementation study, evaluating the relationship between the initiation of this multifaceted  
13 intervention and key process measures. The number of patients anticipated to be enrolled in  
14 to the study was based on a feasibility assessment and using available (but often limited)  
15 hospital statistics. Based on existing information, we have assumed that approximately 300-  
16 500 patients with STEMI will be enrolled in each of the clusters in a 1 year period is  
17 made. The baseline data will be used to compare the outcome after the implementation phase  
18 to measure our study objectives.  
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### 32 ***Study oversight, ethical considerations, and data collection and quality***

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34 This study will be conducted in accordance with the ethical principles that have their origin in  
35 the current declaration of Helsinki and 'ethical guidelines for biomedical research on human  
36 participants' as laid down by the ICMR. Despite the fact that this is a implementation study  
37 focusing on quality improvement, all participating hospitals will still obtain local ethics  
38 committee approval of the study protocol and written informed consent will be obtained from  
39 all participants. The rights, safety and well-being of the study subjects are the most important  
40 considerations and should prevail over interests of society and science.  
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### 51 ***Data collection and quality control:***

52 Data will be collected prospectively from all the participating units from personnel blinded to  
53 the aims of the study. Electronic case report forms (eCRFs) must be completed for each  
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3 patient screened/enrolled and the data for this study will be collected with an electronic data  
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5 capture application. As required by the ICH GCP (International Conference on  
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7 Harmonization Good Clinical Practice) guidelines and regulatory authorities, the investigator  
8  
9 will allow direct access to all pertinent medical records in order to allow the verification of  
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11 data gathered in the eCRFs and for the review of the data collection process. Data will be  
12  
13 captured and processed into a quality assured database. The investigator(s)/institution(s) will  
14  
15 permit study-related monitoring, audits, and regulatory inspection(s), providing direct access  
16  
17 to source data documents. Periodic quality check will be done to ensure proper functioning  
18  
19 and co-ordination of TN-STEMI network (hub and spoke model), timely transmission to  
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21 Class A/Class B hospitals and to minimize treatment delays. Periodic Quality Improvement  
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23 (QI) reports will be generated for every participating hub hospital to ensure that quality  
24  
25 systems are in place. QI will include a review of system administration/ organizational  
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27 activities, pre-hospital and hospital care. It will also have a documentation of effectiveness of  
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29 hospitals and EMS service. A Data and Device Safety Monitoring Board (DDSMB) will  
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31 periodically review and evaluate the accumulated study data for participant safety, study  
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33 conduct, study progress, and make recommendations concerning the continuation,  
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35 modification, or termination of the project.  
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## 43 **Discussion**

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45 Reperfusion therapy is critical in the management of patients with STEMI and one of the  
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47 most powerful predictors of early and late survival; however, its use is considerably  
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49 hampered by several non-clinical and system-related barriers in low-to-middle income  
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51 countries like India. Furthermore, primary PCI has increasingly become the preferred method  
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53 of reperfusion therapy in STEMI management but because of the additional resources that it  
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55 requires it is frequently unavailable in these settings. Expanding population-wide availability  
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3 of reperfusion therapy, primary PCI and early invasive risk stratification are critical aspects  
4  
5 of STEMI systems of care that have been used with great success in Western Europe and  
6  
7 North America.  
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10 We believe that the TN-STEMI programme will create new opportunities to deliver  
11 these therapies in India by addressing various clinical, logistical and societal factors. As in  
12 other countries, effective management of STEMI at the community level in India will require  
13 executing proven treatment protocols along with efficient and rapid inter hospital transfer  
14 within coordinated hospital networks. Regional systems of care such as “Mission: Lifeline”  
15 have been successfully used in STEMI management in the US (8). In Europe, ‘hub and  
16 spoke’ model of STEMI networks also demonstrate improved adherence to reperfusion  
17 therapy and timely treatment strategies (9) and are gaining endorsement through the Stent-  
18 For-Life programme of the European Society of Cardiology. Although STEMI management  
19 in India may also benefit from such organized systems of care, there are little or no data to  
20 support that these approaches improve key processes of care or outcomes in this environment.  
21 Hence, understanding the effect of the STEMI network implemented in the state of  
22 Tamilnadu will have substantial implications for the country. This approach is particularly  
23 worthwhile as it leverages unique public and private partnerships, technological innovation in  
24 monitoring devices, an expanding EMRI ambulance system, and novel strategies for  
25 reperfusion therapy and early invasive risk stratification. If successful, this type of network  
26 may be extended to the rest of India and even worldwide.  
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**Contributions of authors:**

Dr. Thomas Alexander, Dr. Ajit S Mulasari: Conception of trial design and provided the important intellectual content

Dr. Suma M Victor: Drafting of the article

Dr. Ganesh Veerasekar: Drafting of tables and Images

Dr. Kala Subramaniam: Provided the statistical design

Dr. Brahmajee K Nallamothe: Final correction & approval of the version

**Disclosures:**

This study is funded by 'STEMI India'. This study has been accepted by Indian Council of Medical Research and is still awaiting release of funds.

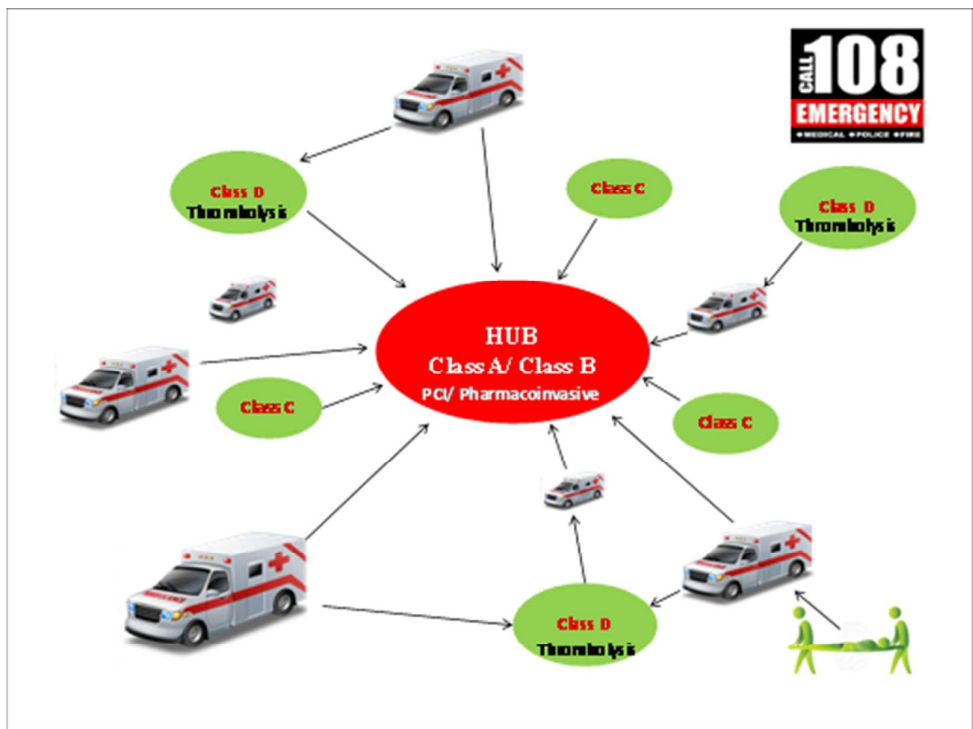
Conflict of interests: The author(s) declare that they have no conflicting interests.

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<b>CLUSTER 1:</b>		
<b>HUB HOSPITAL</b>	<b>SPOKE HOSPITAL</b>	<b>CLASS</b>
Kovai Medical Centre & Hospital, Coimbatore (Class A)	The Pollachi Cardiac Centre, Pollachi	Class D
	SAS Clinic Cardiac Centre, Dharapuram	Class D
	Amaravathy Hospital, Karur	Class D
	TMF Hospital, Tirupur	Class D
	Sri Kuppusamy Hospital, Tirupur	Class D
	Ramya Nursing Home, Nambiyur	Class C
	Sri Kumaran Hospital, Tirupur	Class D
	CFH Hospital, Oddanchathiram	Class D
Recently Added	Coimbatore Medical College Hospital	Class D
	Tirupur General Hospital, Tirupur	Class D
	Dharapuram GH	Class D
	Ooty GH	Class D
	Mettupalayam GH	Class C
	Udumalpet GH	Class D
	Pollachi Government Hospital	Class C
<b>CLUSTER 2:</b>		
<b>HUB HOSPITAL</b>	<b>SPOKE HOSPITAL</b>	<b>CLASS</b>
Madras Medical Mission, Chennai (Class A)	Velammal Hospital, Chennai	Class D
	Sundaram Medical Foundation, Chennai	Class D
	Dr. Mohan's Diabetes Specialities Centre, Chennai	Class D
Proposed Hospitals		
	Thiruvanmayur Government Hospital, Thiruvanmayur	Class D
	Kanchipuram Government Hospital,	Class D



	Kanchipuram	
<b>CLUSTER 3:</b>		
<b>HUB HOSPITAL</b>	<b>SPOKE HOSPITAL</b>	<b>CLASS</b>
Christian Medical College, Vellore (Class A)	LCECU Hospital, Vellore	Class C
	Narayani Hospital & Research Centre, Vellore	Class D
	Scudder Memorial Hospital, Ranipet	Class D
	Rusha Hospital, Vellore	Class D
	CHAD Hospital, Vellore	Class D
	S.L.R. & T.C. Hospital, Karigiri	Class D
	Bethesda Hospital, Ambur	Class D
Proposed Hospitals		
	Vellore Medical College Hospital, Vellore	Class D
<b>CLUSTER 4:</b>		
<b>HUB HOSPITAL</b>	<b>SPOKE HOSPITAL</b>	<b>CLASS</b>
Stanley Medical College, Chennai(Class A)	Government Hospital Thiruvallur.	Class D
	Kilpauk Medical College Chennai.	Class D
	Primary Health Center, Gummidipundi.	Class C
	Government Hospital Chengalpet.	Class D
	Proposed Hospitals	
	All approved private hospitals around Stanley Hospitals, Chennai	Class C/D

## Appendix:

Table 1: Provision of software to STEMI team

STEMI Software	Paramedic	STEMI coordinator	On- Call Cardiologist	STEMI coordinating Centre
Hand held device	Android 4.0 – ‘Ice Cream Sandwich’ , 2G or 3G connectivity	Android 4.0 – ‘Ice Cream Sandwich’ , 2G or 3G connectivity	Samsung Galaxy Tab 2 P 310, 2G or 3G connectivity	-
ECG Device/Monitor	connected via USB cable to the hand held device	-	-	-
Transmitting device	Intel® Atom™ processor N450 at 1.66G Hz	Intel® Atom™ processor N450 at 1.66G Hz	-	-
Data Server	-	-	-	Hosted application: Windows 2008 R2 Standard, SQL Server 2008 R2 Standard Edition

**Table 2: ECG signal specifications:**

Electrodes / leads	Standard 10 lead patient cable / 12lead ECG
Frequency response	0.05 to 125 Hz
Leakage current	< 10 micro amps
CMRR	> 100 dB
Input impedance	> 4 M ohms
Filter	To suppress supply frequency fluctuations
A/D conversion resolution	12 bit
Sampling rate	500 samples/sec
Defibrillator protection	Pulse characteristics of 5kV potential , pulse duration (5 to 20 ms), carrying energy of 360 joules

**Table 3: Arterial saturation (SaO<sub>2</sub>) signal specification:**

Method	Pulse oximetry with finger clip sensors
Range	0-100%
Accuracy	SaO <sub>2</sub> > 70% +/- 2% Pulse rate: +/- 2 bpm
Time required for calculation	<10 seconds
Refresh rate	10 seconds

**Table 4: Blood pressure (BP) signal specification:**

Operating mode	Non-supervised continuous operation
Type of measurement	Oscillometric
Pressure range	0-300 mmHg
Pressure accuracy	±3 mmHg
Measurement ranges for adults – Systolic BP Diastolic BP Mean arterial BP	25 - 280 mmHg 10 - 220 mmHg 15 - 260 mmHg
Air leakage rate of the system	< 3 mmHg / minute
Time required for BP measurement	within 30 seconds, and upto maximum of 90 seconds.

**Table 5: Battery details**

Type	Rechargeable Lithium Ion 7.4V – 4000 mA
Typical working hours	Upto 6 hours of backup
Charging time	8 hours for full charge in standard charging mode
Indicator	Charging and full charge indicator

**Table 6: Display Device Specifications**

(Make : Connoi SmartBook Convertible ST10160)

Processor/chipset	Intel® Atom™ processor N450 at 1.66G Hz Chipset: Intel® NM10 Express
Memory	1GB / 2GB
Storage Device	2.5" SATA HDD (Supports 32G/16G/8G SATA Flash)
Operating System	Android 4.0
LCD	10.1" 1024 x 600 water resistant touch screen <ul style="list-style-type: none"> <li>• 10.1" 1366x768 optional display</li> <li>• Convertible: traditional or touch-optimized tablet mode</li> <li>• Palm-resting feature allows to write and draw comfortably</li> </ul>
Connectivity	10M/100M Ethernet 802.11b/g/n WLAN <ul style="list-style-type: none"> <li>• 3G</li> <li>• GPS</li> </ul>
Keyboard/touch Pad	<ul style="list-style-type: none"> <li>• Water resistant keyboard</li> <li>• Water resistant touch pad (integrated vertical scrolling)</li> <li>• Anti-microbial keyboard</li> </ul>
Battery	4-cell battery (4.8 hrs) (2200mAh cell)
System I/O	2 x USB 2.0 ports, 1 SD slot, VGA port ,1 half sized mini-card slot and 1 full sized mini-card slot, dual audio jacks
Built-in 1.3MPX rotating Camera	30fps (640 x 480) 1.3MP rotatable
Accelerometer	Tilt the Intel-powered convertible classmate PC and the display switches smoothly from portrait to landscape HDD Protection
Handle	Integrated retractable handle to support micro-mobility
Custom Mini-Chassis	<ul style="list-style-type: none"> <li>• Size including handle: 268mm x (39.5~32mm)</li> </ul>

	x 214mm • Weight: 1.52–1.74Kg
Drop Test	Flash 70cm/HDD 60cm

**Table 7: Carry case specifications**

Weight	< 4.5 Kg
Carry case size	330 mm x 210 mm x 110 mm
Material	Industrial grade ABS



**A prospective, controlled study of assertive and timely reperfusion for patients with ST-segment elevation myocardial infarction in Tamil Nadu- The TN-STEMI Programme**

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2013-003850.R1
Article Type:	Protocol
Date Submitted by the Author:	16-Oct-2013
Complete List of Authors:	Alexander, Thomas; Kovai Medical Center and Hospital, Interventional Cardiology Nallamothe, Brahmajee; University of Michigan, Victor, Suma; Madras Medical Mission Hospital, Interventional Cardiology Mullasari, Ajit; Madras Medical Mission Hospital, Interventional Cardiology Veerasekar, Ganesh; Kovai Medical Center and Hospital, Epidemiology Subramaniam, Kala; Lotus Clinical Research Academy Pvt. Ltd, Clinical Research
<b>Primary Subject Heading</b>:	Cardiovascular medicine
Secondary Subject Heading:	Health services research, Epidemiology, Global health, Public health, Medical education and training
Keywords:	Cardiac Epidemiology < CARDIOLOGY, Coronary heart disease < CARDIOLOGY, Myocardial infarction < CARDIOLOGY, Ischaemic heart disease < CARDIOLOGY

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6 **A prospective, controlled study of assertive and timely reperfusion for**  
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8 **patients with ST-segment elevation myocardial infarction in Tamil Nadu**  
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12 **The TN-STEMI Programme**  
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15 Thomas Alexander, Suma M Victor, Ajit S Mulasari, Ganesh Veerasekar, Kala  
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17 Subramaniam, Brahmajee K Nallamothu  
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19 For TN-STEMI Programme Investigators  
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24 **Abstract**  
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26  
27 **Introduction:** Over the last two decades, India has witnessed a staggering increase in the  
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29 incidence and mortality of ST-elevation myocardial infarction (STEMI). Indians have higher  
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31 rates of STEMI and younger populations that suffer from it when compared with developed  
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33 countries. Yet recommended reperfusion therapy with fibrinolysis and percutaneous coronary  
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35 intervention (PCI) are available to only a minority of patients. This gap in care is a result of  
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37 financial barriers, limited healthcare infrastructure, and poor knowledge and accessibility of  
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39 acute medical services for a majority of its population.  
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43 **Methods and analysis:** This is a prospective, multi-centre, “pre test/post test” Quasi-  
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45 experimental, community-based study. This programme will use a ‘hub-and-spoke’  
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47 model of an integrated healthcare network based on clusters of primary-care health  
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49 clinics, small hospitals and large tertiary-care facilities. It is an “all-comers” study  
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51 which will enrol consecutive patients presenting with STEMI to the participating  
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53 hospitals. The primary objectives of the study is to improve the use of reperfusion  
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55 therapy and reduce the time from first medical contact to device or drug in STEMI  
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3 patients; and to increase rates of early invasive risk stratification with coronary  
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5 angiography within 3 to 24 hours of fibrinolytic therapy in eligible patients through  
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7 changes in process of care. Outcomes will be measured with statistical comparison made  
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9 before and after implementing the TN STEMI programme. The estimated sample size is  
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11 based on the Kovai Erode Pilot study, which provided initial work on establishing this  
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13 type of programme in South India. It will be adequately powered at 80% with a  
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15 superiority margin of 10% if 36 patients are enrolled per cluster or 108 patients in 3  
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17 clusters. Thus, the enrolment period of 9 months will result in a sample size of 1500  
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19 patients.  
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24 **Ethics:** This study will be conducted in accordance with the ethical principles that have their  
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26 origin in the current declaration of Helsinki and 'ethical guidelines for biomedical research  
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28 on human participants' as laid down by the Indian Council for Medical Research. All  
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30 participating hospitals will still obtain local ethics committee approval of the study protocol  
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32 and written informed consent will be obtained from all participants.  
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36 **Dissemination and results:** Our findings will be reported through scientific publications,  
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38 research conferences, and public policy venues aimed at state and local governments in India.  
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40 If successful this model can be extended to other areas of India as well as serve as a model of  
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42 STEMI systems of care for low-and-middle income countries across the world.  
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46 **Registration:** Trial is registered with Clinical trial registry of India, No:  
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## Introduction

In the last 40 years cardiovascular disease in India has quadrupled, and by 2020, estimates suggest that almost 60% of patients with cardiovascular disease worldwide will be Indian (1). One of the most ominous manifestations of cardiovascular disease is ST elevation myocardial infarction (STEMI), which carries a grave prognosis if not treated promptly using reperfusion therapy to re-establish flow in the occluded coronary artery (2). Unfortunately, national registry data from 89 cities suggest that Indian patients with STEMI frequently fail to receive adequate reperfusion therapy and to a greater extent than comparable patients in developed countries (3). For example, reperfusion therapy with fibrinolysis is received by less than 60% of Indian patients with STEMI and those that undergo it often do so after great delays. Furthermore, few patients go on to early invasive evaluations and less than 10% receive percutaneous coronary intervention (PCI) during their hospitalization despite growing support for this type of pharmacoinvasive approach. Improving access to these critical treatments is a key opportunity to improve STEMI care that has large implication for India as the epidemic of cardiovascular diseases continues to grow.

However, the challenges to improving STEMI care in India are formidable and include non-clinical factors, such as financial barriers, limited healthcare infrastructure, and poor accessibility of acute medical services for a majority of its population. We therefore previously designed the Kovai Erode Pilot STEMI Study to assess the feasibility of developing a treatment model for STEMI in India based on analogous “systems of care” developed in North America and Europe (4). This study was done in the rural district of Erode, located in the Northern part of Tamilnadu. As a proof-of-concept study it demonstrated that by linking several smaller, peripheral “spoke” hospitals with a centrally-located, PCI-capable “hub” hospital, the use and timelines of reperfusion therapy could be

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3 improved. Encouraged by these results, we now propose a broader ‘hub and spoke’ model in  
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5 other areas of Tamilnadu: the TN-STEMI programme. The purpose of this paper is to  
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7 describe the framework and methods associated with this programme – the first-ever, multi-  
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9 centre study that aims to improve delivery of reperfusion therapy in India. If successful, this  
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11 programme can be extended to other areas of the country and serve as a model of STEMI  
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13 systems of care for low-and-middle income countries.  
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## 16 17 **Methods & Analysis**

### 18 19 *Study design and objectives*

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21 **The TN- STEMI programme is a prospective, controlled, multi-centre pre test/post test**  
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23 **Quasi- experimental study that has been planned as a community-based treatment**  
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25 **programme for improving use and timeliness of reperfusion therapy in patients**  
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27 **diagnosed with STEMI as confirmed by an ECG.** It involves a stepwise approach that  
28  
29 facilitates rapid and definitive restoration of coronary blood flow using a combination of  
30  
31 pharmacological and mechanical reperfusion therapies based on the presentation of the  
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33 patient. This programme will use a ‘hub-and-spoke’ model that relies on an integrated  
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35 healthcare network based on clusters of primary-care health clinics and small hospitals built  
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37 around 4 large tertiary-care facilities that are capable of providing advanced cardiovascular  
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39 services, including PCI and cardiac surgery. The primary objectives of the TN-STEMI  
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41 programme is to use organized systems of care to: (1) improve the use of reperfusion therapy  
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43 and reduce the time from first medical contact to device or drug in STEMI patients; and (2)  
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45 increase rates of early invasive risk stratification in eligible patients **by employing a**  
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47 **pharmacoinvasive strategy of reperfusion.**  
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3 We plan to measure our ability to achieve this overall objective through explicit  
4 measurement of changes in processes of care before and after introduction of the TN STEMI  
5 programme. Secondary (and implicit) objectives include:  
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9 • Integrating care between emergency medical services (EMS) and acute-care clinics  
10 and hospitals at the community level in India, especially in rural areas.  
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- 12 • Providing a pragmatic model to understand the challenges associated with developing  
13 a national STEMI programme in India.  
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- 15 • To increase public awareness of appropriate STEMI care in India  
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### 22 23 ***Study population, facilities and enrolment period***

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25 The TN-STEMI programme incorporates an inclusive, “all-comers” study design.  
26 Consecutive patients aged 20 years or older with symptoms or signs consistent with acute  
27 coronary syndromes and ECG confirmation of STEMI will be enrolled. For entry into the  
28 study, an ECG must have evidence of myocardial injury showing  $\geq 1$ -mm ST-segment  
29 elevation in at least 2 anatomically contiguous limb leads (aVL to III, including -aVR),  $\geq 1$ -  
30 mm ST-segment elevation in a precordial lead V4 through V6,  $\geq 2$ -mm ST-segment elevation  
31 in V1 through V3 or a new left bundle branch block.  
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41 Both “hub” hospitals and “spoke” hospitals are included in each of the 4 clusters. The  
42 hub hospitals are 4 large tertiary-care hospitals with the capability for emergency cardiac  
43 catheterization and PCI (Table 1). Participating hub hospitals are divided into class A or B  
44 facilities depending upon the availability of around-the-clock PCI at the hospital. The spoke  
45 hospitals have been selected based on their proximity to the hub hospitals. Spoke hospitals  
46 situated within 30 minutes of a hub hospital have been classified as class C while those  
47 beyond 30 minutes were class D hospitals. All participating units had to commit to  
48 complying with the study protocol and were required to be within the catchment area for  
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3 available emergency ambulance services. Details of the hub-and-spoke model are discussed  
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5 below.  
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8 Baseline data on management and outcomes of STEMI patients will be collected for 3  
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10 months at all the participating hospitals during an enrolment period that started in the fall of  
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12 2012. The enrolment period will be “rolling” for each of the hospitals and followed by 9  
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14 months of post-implementation data collection on STEMI patients after execution of the TN-  
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16 STEMI programme. Outcomes that we will be evaluating are discussed in detail below and  
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18 include data on processes of care that will be available during the hospitalization and follow  
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20 up data for one year from the index event; the 1 year follow up will either be a hospital visit,  
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22 if it is the routine practice at the local site or a telephonic follow up if hospital visit is not  
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24 required by the treating hospital. Estimated loss to follow up is 20%. **This estimate is based**  
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26 **on our experiences with clinical research in these communities and is conservative.**  
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### 29 30 **TN-STEMI programme: the hub and spoke model**

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32 We have organized the network of hospitals within the TN-STEMI programme using a “hub-  
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34 and-spoke” model that recognizes four classes of healthcare facilities that care for STEMI  
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36 patients in India:  
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40 • **Class A Hospital** - Class A hospitals are PCI-capable hospitals with healthcare teams  
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42 available 24/7 for managing STEMI and its complications. Patients admitted to these  
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44 hospitals typically undergo primary PCI with an aim of door-to-balloon time less than  
45  
46 90 minutes.  
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49 • **Class B Hospital** - These are PCI-capable hospitals, but primary PCI cannot be  
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51 performed outside of working hours. Patients admitted to a class B hospital outside of  
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53 working hours are typically are treated with fibrinolysis with a goal of door-to-needle  
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55 time less than 30 minutes. Patients would be taken for catheterization within the next  
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57 3 to 24 hours, in the same hospital, and undergo PCI, if indicated. Patients at this class  
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of hospitals may undergo primary PCI (like a Class A Hospital) if the patient arrives during working hours.

- **Class C Hospital** – These are healthcare facilities and hospital with the capability to perform and transmit ECGs *and* that are located within 30 minutes of a Class A or Class B hospital. **These hospitals do not have fibrinolysis capability.** All Class C hospitals would constitute the spokes of the Class A/B hospitals. Upon confirmation of STEMI, the class C hospitals will activate GVK-EMRI ambulance, transmit the ECG and transfer the patient to a Class A/B hospital, **depending on the availability primary PCI.** This process of transfer should ideally take less than 60 minutes.
- **Class D Hospital** - This class of healthcare facilities and hospitals have the capability to perform and transmit ECGs *but* are located beyond 30 minutes of PCI-capable hospital. All of these are capable of providing fibrinolysis. All Class D hospitals would constitute the spokes of Class A/B hospitals. Patients arriving at a Class D hospital are treated with fibrinolysis after confirmation of STEMI as per routine hospital practice. After informing the receiving hospital that is linked to it, transfer of the patient via GVK-EMRI ambulance for urgent catheterization and, if indicated PCI, within the next 3 to 24 hours.

Each Class A/B hospital will be linked to approximately 3 to 15 referring Class C/D hospitals. A full list of the participating hospitals organized by their classes is presented in Table 1. Figure 1 shows the “hub-and-spoke” model; Figure 2 shows a geographical map of Tamilnadu State showing locations of clusters of “hub-and-spoke” hospitals in the TN-STEMI programme.

### **Key partners in TN-STEMI programme**

The TN-STEMI programme involves 3 key partners from both the public and private sectors:

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1. **Government of Tamilnadu – Chief Minister’s Health Insurance Scheme.** A

recent and important development that is relevant to the TN-STEMI programme in India has been the establishment and growth of government-sponsored social insurance coverage for healthcare among those below the poverty line. This has been a state-based development, including the Chief Minister’s Health Insurance Scheme in Tamilnadu. All the hub and spoke hospitals in each cluster will be covered by this programme. This requirement will ensure that patients from all social classes can receive timely and suitable treatment for STEMI with no out-of-pocket expenses incurred for their hospitalization. The Chief Minister’s Health Insurance scheme is currently operated by 3 insurance companies: Tiruvellore Thattai Krishnamachari TTK Healthcare, MediAssist and MD India Third Party Administrator.

2. **EMRI Ambulance.** Gunapati Venkata Krishna Emergency Management and Research Institute (GVK-EMRI) operates as a public-private-partnership and is recognized as a not-for-profit entity. It is an organization that has pioneered the development of emergency medical services (EMS) in India, including training paramedics, technicians, nurses and physicians in emergency care. GVK-EMRI ambulance services may be activated by a patient with chest pain or a healthcare facility using the” Call 108” system. Units within this EMS are capable of acquiring ECGs, transmitting ECGs to an ‘on call cardiologist’ for STEMI confirmation, locating the nearest PCI-capable hospital using GPS provided by a coordinating centre, and transferring the patient to the closest hospital. GVK-EMRI ambulances will also transport patients from the spoke hospital to the hub hospitals after initial evaluation and possible treatment.

3. **STEMI-India.** STEMI-India is a not-for-profit entity dedicated to STEMI care in India led by physicians from across the country. The purpose of this organization is to

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2  
3 review and disseminate the latest information from across the world on STEMI  
4 management to providers involved in STEMI care in India; to help organize and train  
5 STEMI teams in hospitals; and to develop STEMI systems of care appropriate to the  
6 context of healthcare systems' needs and resources in India. Other goals include:  
7 facilitating and contributing to national STEMI guidelines within India and improving  
8 public education to reduce delays in accessing care. The organization's role in the  
9 TN-STEMI programme has been to provide expertise in the development and  
10 oversight of the study protocol to meet standards of care within India for STEMI  
11 patients.  
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23 In addition to the 3 key partners above, we have partnered with 2 technology firms, Aosta and  
24 Maestro technologies, to coordinate the development of novel software and hardware  
25 (described below). Finally, Lotus Clinical Research Academy Pvt. Ltd has been involved  
26 with the clinical administration of the trial. The TN-STEMI programme is supported by an  
27 independent grant from the Indian Council for Medical Research (ICMR).  
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### 34 **STEMI Technology**

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37 A novel aspect of the TN-STEMI programme is the implementation of new hardware and  
38 software components to optimize the performance and transmission of ECGs and other  
39 clinical information across the network of hospitals in India by paramedics, nurses and  
40 physicians. The hardware will comprise of the 'STEMI Kit' (Figure 3) that includes:  
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- 46 1. ***ECG recording device*** - ECG devices will record the patient's ECG which would  
47 then be transmitted by paramedics to a hand held device of the STEMI coordinator in  
48 a hub hospital.  
49
- 50 2. ***Vital signs monitoring device*** - This device will record the patient's vital signs and  
51 hemodynamic status, including pulse oxygen saturation, non-invasive blood pressure,  
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3 heart rate and rhythm strip. This will also permit the transmission of key information  
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5 by paramedics to STEMI coordinators at hub hospitals.  
6

- 7  
8 3. ***Display and transmitting device*** - Each STEMI coordinator will have a hand held  
9  
10 device which collects and transmits data when required with sufficient battery  
11  
12 support. This will allow for communication between STEMI coordinators and on-call  
13  
14 cardiologists at the Class A/B hospitals.  
15

16  
17 Coordination of the hardware units by paramedics, STEMI coordinators and on-call  
18  
19 cardiologists will be performed through unique software applications that are specifically  
20  
21 designed for the TN-STEMI programme to be used across a universal platform for multiple  
22  
23 devices. These are summarized in the Appendix.  
24

25  
26 The paramedic and STEMI coordinators will capture the patient demographic details  
27  
28 along with a checklist for eligibility for fibronolytic therapy. This information along with the  
29  
30 ECG will be transmitted to the on-call cardiologist in that cluster to diagnose STEMI and  
31  
32 decide on initial treatment. The on-call cardiologist receives an alert once these data are  
33  
34 obtained. She (or he) can then go over the patient records, ECG and confirm STEMI. This in  
35  
36 turn alerts the paramedic to transport the patient to the destination based on global positioning  
37  
38 system (GPS) navigation. A dedicated server will be available round the clock to route all  
39  
40 information from one hand held device to the other in ambulance or hospital. Data are  
41  
42 simultaneously stored on the server along with the ECG snapshot which can be accessed by  
43  
44 teams at the receiving hospital.  
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### 48 49 **Treatment Protocols**

50  
51 There will be two strategies to manage STEMI patients and both are adapted from current  
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53 American College of Cardiology/American Heart Association and European Society of  
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3 Cardiology guidelines for the context of the healthcare system of Tamilnadu (5,6). Overall,  
4  
5 these guidelines intend to minimize the total ischemic time (7).  
6

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8 1. *Primary and Rescue PCI*: All patients with STEMI presenting to a Class A hospital,  
9  
10 Class B hospital during working hours, and Class C hospital with an estimated  
11  
12 transportation time of less than 60 minutes will undergo primary PCI. The aim is to  
13  
14 achieve a door-to-balloon time of less than 90 minutes and a first medical contact to  
15  
16 balloon time of less than 120 minutes. Inter-hospital transfer of the patient from a  
17  
18 spoke to a hub hospital is expedited from Class D hospitals if: (1) fibrinolysis is  
19  
20 contraindicated; or (2) unsuccessful fibrinolysis is clinically suspected with failed  
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22 reperfusion (i.e., rescue PCI).  
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- 25  
26 2. *Pharmacoinvasive Strategy*: All patients with STEMI presenting to a Class B hospital  
27  
28 outside of working hours or Class D hospital with anticipated long transportation  
29  
30 times, unless contraindicated, will receive fibrinolysis as per routine hospital practice  
31  
32 with goal of door-to-needle time less than 30 minutes. Patients will then be transferred  
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34 for an early invasive strategy with coronary angiography and PCI, if indicated, within  
35  
36 3 to 24 hours of receiving fibrinolytic therapy.  
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40 All other medical therapy will be at the discretion of the treating physician and the healthcare  
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42 team. However, the use of immediate dual antiplatelet therapy, **in the form of aspirin and**  
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44 **one of the thienopyridine group of drugs such as clopidogrel or prasugrel or ticagrelor**  
45  
46 and anticoagulation with heparin or equivalent drugs is encouraged. Other therapies, such as  
47  
48 morphine, nitroglycerin, beta-blockers and calcium-channel blockerse, are not standardized.  
49

50  
51 All participating units will have a single protocol in place for reperfusion therapy and  
52  
53 cardiac catheterization laboratory activation. Prior to the implementation phase of the TN-  
54  
55 STEMI programme, hospitals will adopt a specific strategy for reperfusion therapy based on  
56  
57 distance, logistics, resources and equipment availability. STEMI kits consisting of  
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3 ‘Operations Manual and Guidelines for Management at First Medical Contact’ will be  
4  
5 circulated. These operations manual detail the interventional strategy at each point of care:  
6  
7 the ambulance, the emergency department, inter-hospital transfer, and the role of the  
8  
9 hospitals. A STEMI coordinator responsible for accurate management of the project will be  
10  
11 identified at each point of system care.  
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14 Patients with chest pain who call ‘108’ will enter the system outside of the hospitals.  
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16 These patients will be picked up by the EMRI ambulance, will have a preliminary ECG  
17  
18 performed in the out-of-hospital setting, vital signs recorded and transmitted to the on- call  
19  
20 cardiologist and STEMI coordinator. Once STEMI is confirmed by the on-call cardiologist,  
21  
22 the ambulance will use GPS to locate the closest hospital in the cluster and re-route the  
23  
24 patient there for appropriate treatment. Even before the patient reaches the hospital, the  
25  
26 STEMI coordinator organizes the cardiac catheterization laboratory (if transport is to hub  
27  
28 hospital) or coronary care unit for fibrinolysis (if transportation is to spoke hospital) based on  
29  
30 the proximity of the patient to the nearest hospital. In the overall protocol for the TN-STEMI  
31  
32 programme, any patient with cardiogenic shock will be taken directly to a Class A/B hospital  
33  
34 for primary PCI, bypassing a referring hospital even if it is the closest hospital.  
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### 39 *Primary and Secondary Outcomes*

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42 Our primary outcomes will be based on care provided during the hospitalization and process  
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44 measures associated with the use of and time to reperfusion therapy. Secondary outcomes  
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46 will be clinical events that occur during the hospitalization and follow-up, although we  
47  
48 recognize that we will be underpowered to detect differences in these events. These are  
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50 detailed below. **The reference group for comparison of the outcomes in this study will be**  
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52 **the pre programme implementation group.**  
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### *Primary Outcomes*

- Use of reperfusion therapy with either fibrinolytic therapy or primary PCI
- Use of timely reperfusion defined as door-to-balloon time  $\leq 90$  minutes or door-to-needle  $\leq 30$  minutes in patients with STEMI treated with primary PCI and fibrinolytic therapy, respectively
- Use of early invasive risk stratification with coronary angiography and PCI in patients treated with fibrinolytic therapy

### *Secondary Outcomes*

- Use of rescue PCI in patients with failed fibrinolysis.
- Composite of the following in-hospital outcomes: mortality, recurrent infarction/ischemia, stroke, major and minor bleeds.
- Composite of the following outcomes at 1-year: all-cause mortality, cardiac mortality, stroke, recurrent infarction/ischemia, major and minor bleeds.
- Use of evidence-based therapies – aspirin, beta-blocker and statin – on admission, at discharge and during follow-up

### *Statistical considerations*

Data from all centres will be combined for analysis. Data will be collected and processed into a quality assured database. Descriptive data will be provided in statistical summary tables and listings. Graphical presentations may also be presented where necessary. Continuous variables will be summarized using descriptive statistics such as mean, standard deviation, coefficient of variation (%), median, minimum and maximum; and the same will be reported. For categorical data, the number and percentage of participants in each category will be reported, along with 95% two-sided confidence intervals (95% CI) where appropriate.

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3 Comparison between patients treated during the enrolment period and post-implementation  
4 periods based on the study outcomes will be tested using applicable test of hypothesis such as  
5 t-test, chi-square test or non parametric tests.  
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10 Eligible patients from the study with reference to the definition of control population  
11 and intervention population will be used for statistical comparison. Control population is  
12 defined as population included prior to implementation of TN-STEMI programme into a  
13 cluster that will provide baseline data for evaluation of operational parameters and outcomes  
14 before and after the intervention (i.e., the enrolment period). Intervention population as per  
15 protocol is defined as patients presenting to hub and spoke centres after initiation of a cluster  
16 into TN-STEMI programme (i.e., the post-implementation period). This will also include  
17 patients who were transferred and completed the study protocol, patients who were  
18 transferred and did not complete the study prior to intervention and post intervention.  
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32 The estimated sample size for the present study that allows for statistical inference for the  
33 primary end point uses as reference the Kovai Erode pilot study (4). It is estimated that the  
34 study would be adequately powered at 80% with a superiority margin of 10% if 36 patients  
35 are enrolled per cluster or 108 patients in 3 clusters. Considering the design of the study (all  
36 comers) and the objective of a state-wide program implementation, the enrolment period of 9  
37 months will result in a sample size of 1500 patients. If the sample size cannot be fulfilled  
38 during the study time frame, the enrolment period will be extended.  
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#### 49 ***Study oversight, ethical considerations, and data collection and quality***

50 This study will be conducted in accordance with the ethical principles that have their origin in  
51 the current declaration of Helsinki and 'ethical guidelines for biomedical research on human  
52 participants' as laid down by the ICMR. Despite the fact that this is a implementation study  
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3 focusing on quality improvement, all participating hospitals will still obtain local ethics  
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5 committee approval of the study protocol and written informed consent will be obtained from  
6  
7 all participants. The rights, safety and well-being of the study subjects are the most important  
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9 considerations and should prevail over interests of society and science.  
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14 ***Data collection and quality control:***

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16 Data will be collected prospectively from all the participating units from personnel blinded to  
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18 the aims of the study. Electronic case report forms (eCRFs) must be completed for each  
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20 patient screened/enrolled and the data for this study will be collected with an electronic data  
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22 capture application. As required by the ICH GCP (International Conference on  
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24 Harmonization Good Clinical Practice) guidelines and regulatory authorities, the investigator  
25  
26 will allow direct access to all pertinent medical records in order to allow the verification of  
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28 data gathered in the eCRFs and for the review of the data collection process. Data will be  
29  
30 captured and processed into a quality assured database. The investigator(s)/institution(s) will  
31  
32 permit study-related monitoring, audits, and regulatory inspection(s), providing direct access  
33  
34 to source data documents. Periodic quality check will be done to ensure proper functioning  
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36 and co-ordination of TN-STEMI network (hub and spoke model), timely transmission to  
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38 Class A/Class B hospitals and to minimize treatment delays. Periodic Quality Improvement  
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40 (QI) reports will be generated for every participating hub hospital to ensure that quality  
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42 systems are in place. QI will include a review of system administration/ organizational  
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44 activities, pre-hospital and hospital care. It will also have a documentation of effectiveness of  
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46 hospitals and EMS service. A Data and Device Safety Monitoring Board (DDSMB) will  
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48 periodically review and evaluate the accumulated study data for participant safety, study  
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50 conduct, study progress, and make recommendations concerning the continuation,  
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52 modification, or termination of the project.  
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## Discussion

Reperfusion therapy is critical in the management of patients with STEMI and one of the most powerful predictors of early and late survival; however, its use is considerably hampered by several non-clinical and system-related barriers in low-to-middle income countries like India. Furthermore, primary PCI has increasingly become the preferred method of reperfusion therapy in STEMI management but because of the additional resources that it requires it is frequently unavailable in these settings. Expanding population-wide availability of reperfusion therapy, primary PCI and early invasive risk stratification are critical aspects of STEMI systems of care that have been used with great success in Western Europe and North America.

We believe that the TN-STEMI programme will create new opportunities to deliver these therapies in India by addressing various clinical, logistical and societal factors. As in other countries, effective management of STEMI at the community level in India will require executing proven treatment protocols along with efficient and rapid inter hospital transfer within coordinated hospital networks. Regional systems of care such as “Mission: Lifeline” have been successfully used in STEMI management in the US (8). In Europe, ‘hub and spoke’ model of STEMI networks also demonstrate improved adherence to reperfusion therapy and timely treatment strategies (9) and are gaining endorsement through the Stent-For-Life programme of the European Society of Cardiology. Although STEMI management in India may also benefit from such organized systems of care, there are little or no data to support that these approaches improve key processes of care or outcomes in this environment. Hence, understanding the effect of the STEMI network implemented in the state of Tamilnadu will have substantial implications for the country. This approach is particularly worthwhile as it leverages unique public and private partnerships, technological innovation in

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3 monitoring devices, an expanding EMRI ambulance system, and novel strategies for  
4 reperfusion therapy and early invasive risk stratification. If successful, this type of network  
5 may be extended to the rest of India and even worldwide.  
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### 21 **Contributions of authors:**

22  
23 Dr. Thomas Alexander, Dr. Ajit S Mullasari: Conception of trial design and provided the  
24 important intellectual content  
25

26 Dr. Suma M Victor: Drafting of the article  
27

28 Dr. Ganesh Veerasekar: Drafting of tables and Images  
29

30 Dr. Kala Subramaniam: Provided the statistical design  
31

32 Dr. Brahmajee K Nallamothe: Final correction & approval of the version  
33  
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### 38 **Disclosures:**

39 This study is funded by 'STEMI India'. This study has been accepted by Indian Council of  
40 Medical Research and is still awaiting release of funds.  
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44 Conflict of interests: The author(s) declare that they have no conflicting interests.  
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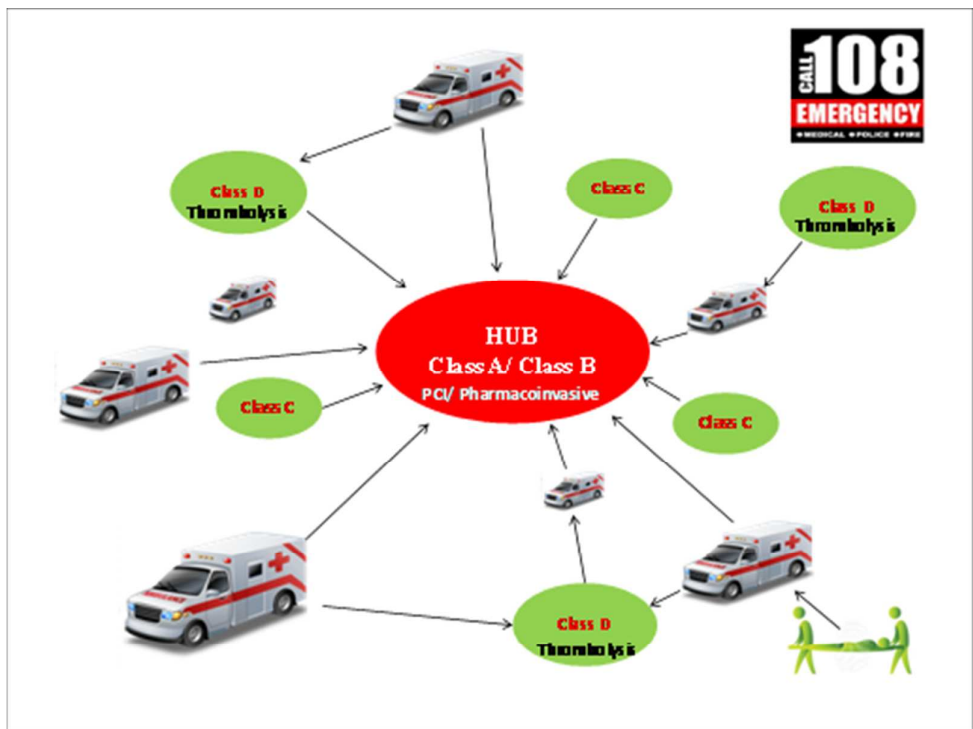
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<b>CLUSTER 1:</b>		
<b>HUB HOSPITAL</b>	<b>SPOKE HOSPITAL</b>	<b>CLASS</b>
Kovai Medical Centre & Hospital, Coimbatore (Class A)	The Pollachi Cardiac Centre, Pollachi	Class D
	SAS Clinic Cardiac Centre, Dharapuram	Class D
	Amaravathy Hospital, Karur	Class D
	TMF Hospital, Tirupur	Class D
	Sri Kuppusamy Hospital, Tirupur	Class D
	Ramya Nursing Home, Nambiyur	Class C
	Sri Kumaran Hospital, Tirupur	Class D
	CFH Hospital, Oddanchathiram	Class D
Recently Added	Coimbatore Medical College Hospital	Class D
	Tirupur General Hospital, Tirupur	Class D
	Dharapuram GH	Class D
	Ooty GH	Class D
	Mettupalayam GH	Class C
	Udumalpet GH	Class D
	Pollachi Government Hospital	Class C
<b>CLUSTER 2:</b>		
<b>HUB HOSPITAL</b>	<b>SPOKE HOSPITAL</b>	<b>CLASS</b>
Madras Medical Mission, Chennai (Class A)	Velammal Hospital, Chennai	Class D
	Sundaram Medical Foundation, Chennai	Class D
	Dr. Mohan's Diabetes Specialities Centre, Chennai	Class D
Proposed Hospitals		
	Thiruvanmayur Government Hospital, Thiruvanmayur	Class D
	Kanchipuram Government Hospital,	Class D

	Kanchipuram	
<b>CLUSTER 3:</b>		
<b>HUB HOSPITAL</b>	<b>SPOKE HOSPITAL</b>	<b>CLASS</b>
Christian Medical College, Vellore (Class A)	LCECU Hospital, Vellore	Class C
	Narayani Hospital & Research Centre, Vellore	Class D
	Scudder Memorial Hospital, Ranipet	Class D
	Rusha Hospital, Vellore	Class D
	CHAD Hospital, Vellore	Class D
	S.L.R. & T.C. Hospital, Karigiri	Class D
	Bethesda Hospital, Ambur	Class D
Proposed Hospitals		
	Vellore Medical College Hospital, Vellore	Class D
<b>CLUSTER 4:</b>		
<b>HUB HOSPITAL</b>	<b>SPOKE HOSPITAL</b>	<b>CLASS</b>
Stanley Medical College, Chennai(Class A)	Government Hospital Thiruvallur.	Class D
	Kilpauk Medical College Chennai.	Class D
	Primary Health Center, Gummidipundi.	Class C
	Government Hospital Chengalpet.	Class D
	Proposed Hospitals	
	All approved private hospitals around Stanley Hospitals, Chennai	Class C/D

## Appendix:

Table 1: Provision of software to STEMI team

STEMI Software	Paramedic	STEMI coordinator	On- Call Cardiologist	STEMI coordinating Centre
Hand held device	Android 4.0 – ‘Ice Cream Sandwich’ , 2G or 3G connectivity	Android 4.0 – ‘Ice Cream Sandwich’ , 2G or 3G connectivity	Samsung Galaxy Tab 2 P 310, 2G or 3G connectivity	-
ECG Device/Monitor	connected via USB cable to the hand held device	-	-	-
Transmitting device	Intel® Atom™ processor N450 at 1.66G Hz	Intel® Atom™ processor N450 at 1.66G Hz	-	-
Data Server	-	-	-	Hosted application: Windows 2008 R2 Standard, SQL Server 2008 R2 Standard Edition

**Table 2: ECG signal specifications:**

Electrodes / leads	Standard 10 lead patient cable / 12lead ECG
Frequency response	0.05 to 125 Hz
Leakage current	< 10 micro amps
CMRR	> 100 dB
Input impedance	> 4 M ohms
Filter	To suppress supply frequency fluctuations
A/D conversion resolution	12 bit
Sampling rate	500 samples/sec
Defibrillator protection	Pulse characteristics of 5kV potential , pulse duration (5 to 20 ms), carrying energy of 360 joules

**Table 3: Arterial saturation (SaO<sub>2</sub>) signal specification:**

Method	Pulse oximetry with finger clip sensors
Range	0-100%
Accuracy	SaO <sub>2</sub> > 70% +/- 2% Pulse rate: +/- 2 bpm
Time required for calculation	<10 seconds
Refresh rate	10 seconds

**Table 4: Blood pressure (BP) signal specification:**

Operating mode	Non-supervised continuous operation
Type of measurement	Oscillometric
Pressure range	0-300 mmHg
Pressure accuracy	±3 mmHg
Measurement ranges for adults – Systolic BP Diastolic BP Mean arterial BP	25 - 280 mmHg 10 - 220 mmHg 15 - 260 mmHg
Air leakage rate of the system	< 3 mmHg / minute
Time required for BP measurement	within 30 seconds, and upto maximum of 90 seconds.



**Table 5: Battery details**

Type	Rechargeable Lithium Ion 7.4V – 4000 mA
Typical working hours	Upto 6 hours of backup
Charging time	8 hours for full charge in standard charging mode
Indicator	Charging and full charge indicator

**Table 6: Display Device Specifications**

(Make : Connoi SmartBook Convertible ST10160)

Processor/chipset	Intel® Atom™ processor N450 at 1.66G Hz Chipset: Intel® NM10 Express
Memory	1GB / 2GB
Storage Device	2.5" SATA HDD (Supports 32G/16G/8G SATA Flash)
Operating System	Android 4.0
LCD	10.1" 1024 x 600 water resistant touch screen <ul style="list-style-type: none"> <li>• 10.1" 1366x768 optional display</li> <li>• Convertible: traditional or touch-optimized tablet mode</li> <li>• Palm-resting feature allows to write and draw comfortably</li> </ul>
Connectivity	10M/100M Ethernet 802.11b/g/n WLAN <ul style="list-style-type: none"> <li>• 3G</li> <li>• GPS</li> </ul>
Keyboard/touch Pad	<ul style="list-style-type: none"> <li>• Water resistant keyboard</li> <li>• Water resistant touch pad (integrated vertical scrolling)</li> <li>• Anti-microbial keyboard</li> </ul>
Battery	4-cell battery (4.8 hrs) (2200mAh cell)
System I/O	2 x USB 2.0 ports, 1 SD slot, VGA port ,1 half sized mini-card slot and 1 full sized mini-card slot, dual audio jacks
Built-in 1.3MPX rotating Camera	30fps (640 x 480) 1.3MP rotatable
Accelerometer	Tilt the Intel-powered convertible classmate PC and the display switches smoothly from portrait to landscape HDD Protection
Handle	Integrated retractable handle to support micro-mobility
Custom Mini-Chassis	<ul style="list-style-type: none"> <li>• Size including handle: 268mm x (39.5~32mm)</li> </ul>

	x 214mm • Weight: 1.52–1.74Kg
Drop Test	Flash 70cm/HDD 60cm

**Table 7: Carry case specifications**

Weight	< 4.5 Kg
Carry case size	330 mm x 210 mm x 110 mm
Material	Industrial grade ABS



**Protocol for a prospective, controlled study of assertive and timely reperfusion for patients with ST-segment elevation myocardial infarction in Tamil Nadu - The TN-STEMI Programme**

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2013-003850.R2
Article Type:	Protocol
Date Submitted by the Author:	23-Oct-2013
Complete List of Authors:	Alexander, Thomas; Kovai Medical Center and Hospital, Interventional Cardiology Nallamothu, Brahmajee; University of Michigan, Victor, Suma; Madras Medical Mission Hospital, Interventional Cardiology Mullasari, Ajit; Madras Medical Mission Hospital, Interventional Cardiology Veerasekar, Ganesh; Kovai Medical Center and Hospital, Epidemiology Subramaniam, Kala; Lotus Clinical Research Academy Pvt. Ltd, Clinical Research
<b>Primary Subject Heading</b>:	Cardiovascular medicine
Secondary Subject Heading:	Health services research, Epidemiology, Global health, Public health, Medical education and training
Keywords:	Cardiac Epidemiology < CARDIOLOGY, Coronary heart disease < CARDIOLOGY, Myocardial infarction < CARDIOLOGY, Ischaemic heart disease < CARDIOLOGY

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6 **Protocol for a prospective, controlled study of assertive and timely**  
7 **reperfusion for patients with ST-segment elevation myocardial infarction**  
8 **in Tamil Nadu**  
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15 **The TN-STEMI Programme**  
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18 Thomas Alexander, Suma M Victor, Ajit S Mulasari, Ganesh Veerasekar, Kala  
19 Subramaniam, Brahmajee K Nallamothu  
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22 For TN-STEMI Programme Investigators  
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27 **Abstract**  
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30 **Introduction:** Over the last two decades, India has witnessed a staggering increase in the  
31 incidence and mortality of ST-elevation myocardial infarction (STEMI). Indians have higher  
32 rates of STEMI and younger populations that suffer from it when compared with developed  
33 countries. Yet recommended reperfusion therapy with fibrinolysis and percutaneous coronary  
34 intervention (PCI) are available to only a minority of patients. This gap in care is a result of  
35 financial barriers, limited healthcare infrastructure, and poor knowledge and accessibility of  
36 acute medical services for a majority of its population.  
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46 **Methods and analysis:** This is a prospective, multi-centre, “pre test/post test” Quasi-  
47 experimental, community-based study. This programme will use a ‘hub-and-spoke’  
48 model of an integrated healthcare network based on clusters of primary-care health  
49 clinics, small hospitals and large tertiary-care facilities. It is an “all-comers” study  
50 which will enrol consecutive patients presenting with STEMI to the participating  
51 hospitals. The primary objectives of the study is to improve the use of reperfusion  
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3 therapy and reduce the time from first medical contact to device or drug in STEMI  
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5 patients; and to increase rates of early invasive risk stratification with coronary  
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7 angiography within 3 to 24 hours of fibrinolytic therapy in eligible patients through  
8  
9 changes in process of care. Outcomes will be measured with statistical comparison made  
10  
11 before and after implementing the TN STEMI programme. The estimated sample size is  
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13 based on the Kovai Erode Pilot study, which provided initial work on establishing this  
14  
15 type of programme in South India. It will be adequately powered at 80% with a  
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17 superiority margin of 10% if 36 patients are enrolled per cluster or 108 patients in 3  
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19 clusters. Thus, the enrolment period of 9 months will result in a sample size of 1500  
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21 patients.  
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26 **Ethics:** This study will be conducted in accordance with the ethical principles that have their  
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28 origin in the current declaration of Helsinki and 'ethical guidelines for biomedical research  
29  
30 on human participants' as laid down by the Indian Council for Medical Research. All  
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32 participating hospitals will still obtain local ethics committee approval of the study protocol  
33  
34 and written informed consent will be obtained from all participants.  
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38 **Dissemination and results:** Our findings will be reported through scientific publications,  
39  
40 research conferences, and public policy venues aimed at state and local governments in India.  
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42 If successful this model can be extended to other areas of India as well as serve as a model of  
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44 STEMI systems of care for low-and-middle income countries across the world.  
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48 **Registration:** Trial is registered with Clinical trial registry of India, No:  
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50 CTRI/2012/09/003002.  
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## Introduction

In the last 40 years cardiovascular disease in India has quadrupled, and by 2020, estimates suggest that almost 60% of patients with cardiovascular disease worldwide will be Indian (1). One of the most ominous manifestations of cardiovascular disease is ST elevation myocardial infarction (STEMI), which carries a grave prognosis if not treated promptly using reperfusion therapy to re-establish flow in the occluded coronary artery (2). Unfortunately, national registry data from 89 cities suggest that Indian patients with STEMI frequently fail to receive adequate reperfusion therapy and to a greater extent than comparable patients in developed countries (3). For example, reperfusion therapy with fibrinolysis is received by less than 60% of Indian patients with STEMI and those that undergo it often do so after great delays (3). Furthermore, few patients go on to early invasive evaluations and less than 10% receive percutaneous coronary intervention (PCI) during their hospitalization despite growing support for this type of pharmacoinvasive approach (3). Improving access to these critical treatments is a key opportunity to improve STEMI care that has large implication for India as the epidemic of cardiovascular diseases continues to grow.

However, the challenges to improving STEMI care in India are formidable and include non-clinical factors, such as financial barriers, limited healthcare infrastructure, and poor accessibility of acute medical services for a majority of its population. We therefore previously designed the Kovai Erode Pilot STEMI Study to assess the feasibility of developing a treatment model for STEMI in India based on analogous “systems of care” developed in North America and Europe (4). This study was done in the rural district of Erode, located in the Northern part of Tamilnadu. As a proof-of-concept study it

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2  
3 demonstrated that by linking several smaller, peripheral “spoke” hospitals with a centrally-  
4 located, PCI-capable “hub” hospital, the use and timelines of reperfusion therapy could be  
5 improved. Encouraged by these results, we now propose a broader ‘hub and spoke’ model in  
6 other areas of Tamilnadu: the TN-STEMI programme. The purpose of this paper is to  
7 describe the framework and methods associated with this programme – the first-ever, multi-  
8 centre study that aims to improve delivery of reperfusion therapy in India. If successful, this  
9 programme can be extended to other areas of the country and serve as a model of STEMI  
10 systems of care for low-and-middle income countries.  
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## 21 **Methods & Analysis**

### 22 *Study design and objectives*

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25 **The TN- STEMI programme is a prospective, controlled, multi-centre pre test/post test**  
26 **Quasi- experimental study that has been planned as a community-based treatment**  
27 **programme for improving use and timeliness of reperfusion therapy in patients**  
28 **diagnosed with STEMI as confirmed by an ECG. RCT design was not chosen for this**  
29 **study, primarily because it was not attempting to prove efficacy of a certain treatment**  
30 **or causality assessment. Instead our goal was more focused on implementation of a**  
31 **program that would facilitate quick recognition and shifting of patients for definitive**  
32 **treatment following a standardised pre hospital care in the challenges of India.** It  
33 involves a stepwise approach that facilitates rapid and definitive restoration of coronary blood  
34 flow using a combination of pharmacological and mechanical reperfusion therapies based on  
35 the presentation of the patient. This programme will use a ‘hub-and-spoke’ model that relies  
36 on an integrated healthcare network based on clusters of primary-care health clinics and small  
37 hospitals built around 4 large tertiary-care facilities that are capable of providing advanced  
38 cardiovascular services, including PCI and cardiac surgery. The primary objectives of the  
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3 TN-STEMI programme is to use organized systems of care to: (1) improve the use of  
4 reperfusion therapy and reduce the time from first medical contact to device or drug in  
5 STEMI patients; and (2) increase rates of early invasive risk stratification in eligible patients  
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10 **by employing a pharmacoinvasive strategy of reperfusion.**

11 We plan to measure our ability to achieve this overall objective through explicit  
12 measurement of changes in processes of care before and after introduction of the TN STEMI  
13 programme. Secondary (and implicit) objectives include:

- 14 • Integrating care between emergency medical services (EMS) and acute-care clinics  
15 and hospitals at the community level in India, especially in rural areas.
- 16 • Providing a pragmatic model to understand the challenges associated with developing  
17 a national STEMI programme in India.
- 18 • To increase public awareness of appropriate STEMI care in India

### 19 20 21 22 23 24 25 26 27 28 29 30 31 32 ***Study population, facilities and enrolment period***

33 The TN-STEMI programme incorporates an inclusive, “all-comers” study design.  
34 Consecutive patients aged 20 years or older with symptoms or signs consistent with acute  
35 coronary syndromes and ECG confirmation of STEMI will be enrolled. For entry into the  
36 study, an ECG must have evidence of myocardial injury showing  $\geq 1$ -mm ST-segment  
37 elevation in at least 2 anatomically contiguous limb leads (aVL to III, including -aVR),  $\geq 1$ -  
38 mm ST-segment elevation in a precordial lead V4 through V6,  $\geq 2$ -mm ST-segment elevation  
39 in V1 through V3 or a new left bundle branch block.  
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49 Both “hub” hospitals and “spoke” hospitals are included in each of the 4 clusters. The  
50 hub hospitals are 4 large tertiary-care hospitals with the capability for emergency cardiac  
51 catheterization and PCI (Table 1). Participating hub hospitals are divided into class A or B  
52 facilities depending upon the availability of around-the-clock PCI at the hospital. The spoke  
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3 hospitals have been selected based on their proximity to the hub hospitals. Spoke hospitals  
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5 situated within 30 minutes of a hub hospital have been classified as class C while those  
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7 beyond 30 minutes were class D hospitals. All participating units had to commit to  
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9 complying with the study protocol and were required to be within the catchment area for  
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11 available emergency ambulance services. Details of the hub-and-spoke model are discussed  
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13 below.

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16 Baseline data on management and outcomes of STEMI patients will be collected for 3  
17  
18 months at all the participating hospitals during an enrolment period that started in the fall of  
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20 2012. **This data includes patient's details with address and telephone number,**  
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22 **demographic details, personal and medical history in detail such as smoking status**  
23  
24 **whether patient is a current smoker or smoker in the past or non smoker, if a smoker,**  
25  
26 **then the details of quantity of consumption and duration will be collected. Clinical**  
27  
28 **examination findings, investigations, diagnosis, treatment modality, medication details,**  
29  
30 **cardiac catheterization details, outcome will be noted. Baseline data will also include**  
31  
32 **assessment of systems of care- how did the patient come to the hospital, total ischemic**  
33  
34 **time, the mode of treatment, transport, time intervals of onset of chest pain, time**  
35  
36 **reached the hospital, time taken to perform ECG, time of starting of treatment etc.** The  
37  
38 enrolment period will be "rolling" for each of the hospitals and followed by 9 months of post-  
39  
40 implementation data collection on STEMI patients after execution of the TN-STEMI  
41  
42 programme. Outcomes that we will be evaluating are discussed in detail below and include  
43  
44 data on processes of care that will be available during the hospitalization and follow up data  
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46 for one year from the index event; the 1 year follow up will either be a hospital visit, if it is  
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48 the routine practice at the local site or a telephonic follow up if hospital visit is not required  
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50 by the treating hospital. Estimated loss to follow up is 20%. **This estimate is based on our**  
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52 **experiences with clinical research in these communities and is conservative.**  
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## TN-STEMI programme: the hub and spoke model

We have organized the network of hospitals within the TN-STEMI programme using a “hub-and-spoke” model that recognizes four classes of healthcare facilities that care for STEMI patients in India:

- **Class A Hospital** - Class A hospitals are PCI-capable hospitals with healthcare teams available 24/7 for managing STEMI and its complications. Patients admitted to these hospitals typically undergo primary PCI with an aim of door-to-balloon time less than 90 minutes.
- **Class B Hospital** - These are PCI-capable hospitals, but primary PCI cannot be performed outside of working hours. Patients admitted to a class B hospital outside of working hours are typically are treated with fibrinolysis with a goal of door-to-needle time less than 30 minutes. Patients would be taken for catheterization within the next 3 to 24 hours, in the same hospital, and undergo PCI, if indicated. Patients at this class of hospitals may undergo primary PCI (like a Class A Hospital) if the patient arrives during working hours.
- **Class C Hospital** – These are healthcare facilities and hospital with the capability to perform and transmit ECGs *and* that are located within 30 minutes of a Class A or Class B hospital. **These hospitals do not have fibrinolysis capability.** All Class C hospitals would constitute the spokes of the Class A/B hospitals. Upon confirmation of STEMI, the class C hospitals will activate GVK-EMRI ambulance, transmit the ECG and transfer the patient to a Class A/B hospital, **depending on the availability primary PCI.** This process of transfer should ideally take less than 60 minutes.
- **Class D Hospital** - This class of healthcare facilities and hospitals have the capability to perform and transmit ECGs *but* are located beyond 30 minutes of PCI-capable hospital. All of these are capable of providing fibrinolysis. All Class D hospitals

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3 would constitute the spokes of Class A/B hospitals. Patients arriving at a Class D  
4 hospital are treated with fibrinolysis after confirmation of STEMI as per routine  
5 hospital practice. After informing the receiving hospital that is linked to it, transfer of  
6 the patient via GVK-EMRI ambulance for urgent catheterization and, if indicated  
7 PCI, within the next 3 to 24 hours.  
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14 Each Class A/B hospital will be linked to approximately 3 to 15 referring Class C/D  
15 hospitals. A full list of the participating hospitals organized by their classes is presented in  
16 Table 1. Figure 1 shows the “hub-and-spoke” model; Figure 2 shows a geographical map of  
17 Tamilnadu State showing locations of clusters of “hub-and-spoke” hospitals in the TN-  
18 STEMI programme.  
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### 25 26 **Key partners in TN-STEMI programme**

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28 The TN-STEMI programme involves 3 key partners from both the public and private sectors:  
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30

- 31 1. **Government of Tamilnadu – Chief Minister’s Health Insurance Scheme.** A  
32 recent and important development that is relevant to the TN-STEMI programme in  
33 India has been the establishment and growth of government-sponsored social  
34 insurance coverage for healthcare among those below the poverty line. This has been  
35 a state-based development, including the Chief Minister’s Health Insurance Scheme  
36 in Tamilnadu. All the hub and spoke hospitals in each cluster will be covered by this  
37 programme. This requirement will ensure that patients from all social classes can  
38 receive timely and suitable treatment for STEMI with no out-of-pocket expenses  
39 incurred for their hospitalization. The Chief Minister’s Health Insurance scheme is  
40 currently operated by 3 insurance companies: Tiruvellore Thattai Krishnamachari  
41 TTK Healthcare, MediAssist and MD India Third Party Administrator.  
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3       **2. EMRI Ambulance.** Gunapati Venkata Krishna Emergency Management and  
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5 Research Institute (GVK-EMRI) operates as a public-private-partnership and is  
6  
7 recognized as a not-for-profit entity. It is an organization that has pioneered the  
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9 development of emergency medical services (EMS) in India, including training  
10  
11 paramedics, technicians, nurses and physicians in emergency care. GVK-EMRI  
12  
13 ambulance services may be activated by a patient with chest pain or a healthcare  
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15 facility using the” Call 108” system. Units within this EMS are capable of acquiring  
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17 ECGs, transmitting ECGs to an ‘on call cardiologist’ for STEMI confirmation,  
18  
19 locating the nearest PCI-capable hospital using GPS provided by a coordinating  
20  
21 centre, and transferring the patient to the closest hospital. GVK-EMRI ambulances  
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23 will also transport patients from the spoke hospital to the hub hospitals after initial  
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25 evaluation and possible treatment.  
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30       **3. STEMI-India.** STEMI-India is a not-for-profit entity dedicated to STEMI care in  
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32 India led by physicians from across the country. The purpose of this organization is to  
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34 review and disseminate the latest information from across the world on STEMI  
35  
36 management to providers involved in STEMI care in India; to help organize and train  
37  
38 STEMI teams in hospitals; and to develop STEMI systems of care appropriate to the  
39  
40 context of healthcare systems’ needs and resources in India. Other goals include:  
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42 facilitating and contributing to national STEMI guidelines within India and improving  
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44 public education to reduce delays in accessing care. The organization’s role in the  
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46 TN-STEMI programme has been to provide expertise in the development and  
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48 oversight of the study protocol to meet standards of care within India for STEMI  
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50 patients.  
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55 In addition to the 3 key partners above, we have partnered with 2 technology firms, Aosta and  
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57 Maestro technologies, to coordinate the development of novel software and hardware  
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(described below). Finally, Lotus Clinical Research Academy Pvt. Ltd has been involved with the clinical administration of the trial. The TN-STEMI programme is supported by an independent grant from the Indian Council for Medical Research (ICMR).

## STEMI Technology

A novel aspect of the TN-STEMI programme is the implementation of new hardware and software components to optimize the performance and transmission of ECGs and other clinical information across the network of hospitals in India by paramedics, nurses and physicians. The hardware will comprise of the 'STEMI Kit' (Figure 3) that includes:

1. **ECG recording device** - ECG devices will record the patient's ECG which would then be transmitted by paramedics to a hand held device of the STEMI coordinator in a hub hospital.
2. **Vital signs monitoring device** - This device will record the patient's vital signs and hemodynamic status, including pulse oxygen saturation, non-invasive blood pressure, heart rate and rhythm strip. This will also permit the transmission of key information by paramedics to STEMI coordinators at hub hospitals.
3. **Display and transmitting device** - Each STEMI coordinator will have a hand held device which collects and transmits data when required with sufficient battery support. This will allow for communication between STEMI coordinators and on-call cardiologists at the Class A/B hospitals.

Coordination of the hardware units by paramedics, STEMI coordinators and on-call cardiologists will be performed through unique software applications that are specifically designed for the TN-STEMI programme to be used across a universal platform for multiple devices. These are summarized in the Appendix.

The paramedic and STEMI coordinators will capture the patient demographic details along with a checklist for eligibility for fibrinolytic therapy. This information along with the

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3 ECG will be transmitted to the on-call cardiologist in that cluster to diagnose STEMI and  
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5 decide on initial treatment. The on-call cardiologist receives an alert once these data are  
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7 obtained. She (or he) can then go over the patient records, ECG and confirm STEMI. This in  
8  
9 turn alerts the paramedic to transport the patient to the destination based on global positioning  
10  
11 system (GPS) navigation. A dedicated server will be available round the clock to route all  
12  
13 information from one hand held device to the other in ambulance or hospital. Data are  
14  
15 simultaneously stored on the server along with the ECG snapshot which can be accessed by  
16  
17 teams at the receiving hospital.  
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## 20 21 22 **Treatment Protocols**

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24 There will be two strategies to manage STEMI patients and both are adapted from current  
25  
26 American College of Cardiology/American Heart Association and European Society of  
27  
28 Cardiology guidelines for the context of the healthcare system of Tamilnadu (5,6). Overall,  
29  
30 these guidelines intend to minimize the total ischemic time (7).  
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- 33  
34 1. *Primary and Rescue PCI*: All patients with STEMI presenting to a Class A hospital,  
35  
36 Class B hospital during working hours, and Class C hospital with an estimated  
37  
38 transportation time of less than 60 minutes will undergo primary PCI. The aim is to  
39  
40 achieve a door-to-balloon time of less than 90 minutes and a first medical contact to  
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42 balloon time of less than 120 minutes. Inter-hospital transfer of the patient from a  
43  
44 spoke to a hub hospital is expedited from Class D hospitals if: (1) fibrinolysis is  
45  
46 contraindicated; or (2) unsuccessful fibrinolysis is clinically suspected with failed  
47  
48 reperfusion (i.e., rescue PCI).  
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- 51  
52 2. *Pharmacoinvasive Strategy*: All patients with STEMI presenting to a Class B hospital  
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54 outside of working hours or Class D hospital with anticipated long transportation  
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56 times, unless contraindicated, will receive fibrinolysis as per routine hospital practice  
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3 with goal of door-to-needle time less than 30 minutes. Patients will then be transferred  
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5 for an early invasive strategy with coronary angiography and PCI, if indicated, within  
6  
7 3 to 24 hours of receiving fibrinolytic therapy.  
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10 All other medical therapy will be at the discretion of the treating physician and the healthcare  
11  
12 team. However, the use of immediate dual antiplatelet therapy, **in the form of aspirin and**  
13  
14 **one of the thienopyridine group of drugs such as clopidogrel or prasugrel or ticagrelor**  
15  
16 and anticoagulation with heparin or equivalent drugs is encouraged. Other therapies, such as  
17  
18 morphine, nitroglycerin, beta-blockers and calcium-channel blockers, are not standardized.  
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21 All participating units will have a single protocol in place for reperfusion therapy and  
22  
23 cardiac catheterization laboratory activation. Prior to the implementation phase of the TN-  
24  
25 STEMI programme, hospitals will adopt a specific strategy for reperfusion therapy based on  
26  
27 distance, logistics, resources and equipment availability. STEMI kits consisting of  
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29 ‘Operations Manual and Guidelines for Management at First Medical Contact’ will be  
30  
31 circulated. These operations manual detail the interventional strategy at each point of care:  
32  
33 the ambulance, the emergency department, inter-hospital transfer, and the role of the  
34  
35 hospitals. A STEMI coordinator responsible for accurate management of the project will be  
36  
37 identified at each point of system care.  
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41 Patients with chest pain who call ‘108’ will enter the system outside of the hospitals.  
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43 These patients will be picked up by the EMRI ambulance, will have a preliminary ECG  
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45 performed in the out-of-hospital setting, vital signs recorded and transmitted to the on- call  
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47 cardiologist and STEMI coordinator. Once STEMI is confirmed by the on-call cardiologist,  
48  
49 the ambulance will use GPS to locate the closest hospital in the cluster and re-route the  
50  
51 patient there for appropriate treatment. Even before the patient reaches the hospital, the  
52  
53 STEMI coordinator organizes the cardiac catheterization laboratory (if transport is to hub  
54  
55 hospital) or coronary care unit for fibrinolysis (if transportation is to spoke hospital) based on  
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3 the proximity of the patient to the nearest hospital. In the overall protocol for the TN-STEMI  
4 programme, any patient with cardiogenic shock will be taken directly to a Class A/B hospital  
5 for primary PCI, bypassing a referring hospital even if it is the closest hospital.  
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### 9 10 *Primary and Secondary Outcomes*

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12 Our primary outcomes will be based on care provided during the hospitalization and process  
13 measures associated with the use of and time to reperfusion therapy. Secondary outcomes  
14 will be clinical events that occur during the hospitalization and follow-up, although we  
15 recognize that we will be underpowered to detect differences in these events. These are  
16 detailed below. **The reference group for comparison of the outcomes in this study will be**  
17 **the pre programme implementation group.**  
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### 32 *Primary Outcomes*

- 33 • Use of reperfusion therapy with either fibrinolytic therapy or primary PCI
- 34 • Use of timely reperfusion defined as door-to-balloon time  $\leq 90$  minutes or door-to-  
35 needle  $\leq 30$  minutes in patients with STEMI treated with primary PCI and fibrinolytic  
36 therapy, respectively
- 37 • Use of early invasive risk stratification with coronary angiography and PCI in patients  
38 treated with fibrinolytic therapy
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### 49 *Secondary Outcomes*

- 50 • Use of rescue PCI in patients with failed fibrinolysis.
- 51 • Composite of the following in-hospital outcomes: mortality, recurrent  
52 infarction/ischemia, stroke, major and minor bleeds.  
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- Composite of the following outcomes at 1-year: all-cause mortality, cardiac mortality, stroke, recurrent infarction/ischemia, major and minor bleeds.
- Use of evidence-based therapies – aspirin, beta-blocker and statin – on admission, at discharge and during follow-up

### *Statistical considerations*

Data from all centres will be combined for analysis. Data will be collected and processed into a quality assured database. Descriptive data will be provided in statistical summary tables and listings. Graphical presentations may also be presented where necessary. Continuous variables will be summarized using descriptive statistics such as mean, standard deviation, coefficient of variation (%), median, minimum and maximum; and the same will be reported. For categorical data, the number and percentage of participants in each category will be reported, along with 95% two-sided confidence intervals (95% CI) where appropriate. Comparison between patients treated during the enrolment period and post-implementation periods based on the study outcomes will be tested using applicable test of hypothesis such as t-test, chi-square test or non parametric tests.

Eligible patients from the study with reference to the definition of control population and intervention population will be used for statistical comparison. Control population is defined as population included prior to implementation of TN-STEMI programme into a cluster that will provide baseline data for evaluation of operational parameters and outcomes before and after the intervention (i.e., the enrolment period). Intervention population as per protocol is defined as patients presenting to hub and spoke centres after initiation of a cluster into TN-STEMI programme (i.e., the post-implementation period). This will also include patients who were transferred and completed the study protocol, patients who were transferred and did not complete the study prior to intervention and post intervention.

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3 The estimated sample size for the present study that allows for statistical inference for the  
4 primary end point uses as reference the Kovai Erode pilot study (4). It is estimated that the  
5 study would be adequately powered at 80% with a superiority margin of 10% if 36 patients  
6 are enrolled per cluster or 108 patients in 3 clusters. Considering the design of the study (all  
7 comers) and the objective of a state-wide program implementation, the enrolment period of 9  
8 months will result in a sample size of 1500 patients. If the sample size cannot be fulfilled  
9 during the study time frame, the enrolment period will be extended.  
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### 20 ***Study oversight, ethical considerations, and data collection and quality***

21 This study will be conducted in accordance with the ethical principles that have their origin in  
22 the current declaration of Helsinki and 'ethical guidelines for biomedical research on human  
23 participants' as laid down by the ICMR. Despite the fact that this is a implementation study  
24 focusing on quality improvement, all participating hospitals will still obtain local ethics  
25 committee approval of the study protocol and written informed consent will be obtained from  
26 all participants. The rights, safety and well-being of the study subjects are the most important  
27 considerations and should prevail over interests of society and science.  
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### 40 ***Data collection and quality control:***

41 Data will be collected prospectively from all the participating units from personnel blinded to  
42 the aims of the study. Electronic case report forms (eCRFs) must be completed for each  
43 patient screened/enrolled and the data for this study will be collected with an electronic data  
44 capture application. As required by the ICH GCP (International Conference on  
45 Harmonization Good Clinical Practice) guidelines and regulatory authorities, the investigator  
46 will allow direct access to all pertinent medical records in order to allow the verification of  
47 data gathered in the eCRFs and for the review of the data collection process. Data will be  
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3 captured and processed into a quality assured database. The investigator(s)/institution(s) will  
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5 permit study-related monitoring, audits, and regulatory inspection(s), providing direct access  
6  
7 to source data documents. Periodic quality check will be done to ensure proper functioning  
8  
9 and co-ordination of TN-STEMI network (hub and spoke model), timely transmission to  
10  
11 Class A/Class B hospitals and to minimize treatment delays. Periodic Quality Improvement  
12  
13 (QI) reports will be generated for every participating hub hospital to ensure that quality  
14  
15 systems are in place. QI will include a review of system administration/ organizational  
16  
17 activities, pre-hospital and hospital care. It will also have a documentation of effectiveness of  
18  
19 hospitals and EMS service. A Data and Device Safety Monitoring Board (DDSMB) will  
20  
21 periodically review and evaluate the accumulated study data for participant safety, study  
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23 conduct, study progress, and make recommendations concerning the continuation,  
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25 modification, or termination of the project.  
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## 32 **Discussion**

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34 Reperfusion therapy is critical in the management of patients with STEMI and one of the  
35  
36 most powerful predictors of early and late survival; however, its use is considerably  
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38 hampered by several non-clinical and system-related barriers in low-to-middle income  
39  
40 countries like India. Furthermore, primary PCI has increasingly become the preferred method  
41  
42 of reperfusion therapy in STEMI management but because of the additional resources that it  
43  
44 requires it is frequently unavailable in these settings. Expanding population-wide availability  
45  
46 of reperfusion therapy, primary PCI and early invasive risk stratification are critical aspects  
47  
48 of STEMI systems of care that have been used with great success in Western Europe and  
49  
50 North America.  
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53  
54 We believe that the TN-STEMI programme will create new opportunities to deliver  
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56 these therapies in India by addressing various clinical, logistical and societal factors. As in  
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3 other countries, effective management of STEMI at the community level in India will require  
4  
5 executing proven treatment protocols along with efficient and rapid inter hospital transfer  
6  
7 within coordinated hospital networks. Regional systems of care such as “Mission: Lifeline”  
8  
9 have been successfully used in STEMI management in the US (8). In Europe, ‘hub and  
10  
11 spoke’ model of STEMI networks also demonstrate improved adherence to reperfusion  
12  
13 therapy and timely treatment strategies (9) and are gaining endorsement through the Stent-  
14  
15 For-Life programme of the European Society of Cardiology. Although STEMI management  
16  
17 in India may also benefit from such organized systems of care, there are little or no data to  
18  
19 support that these approaches improve key processes of care or outcomes in this environment.  
20  
21 Hence, understanding the effect of the STEMI network implemented in the state of  
22  
23 Tamilnadu will have substantial implications for the country. This approach is particularly  
24  
25 worthwhile as it leverages unique public and private partnerships, technological innovation in  
26  
27 monitoring devices, an expanding EMRI ambulance system, and novel strategies for  
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29 reperfusion therapy and early invasive risk stratification. If successful, this type of network  
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31 may be extended to the rest of India and even worldwide.  
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#### 48 **Contributions of authors:**

49 Dr. Thomas Alexander, Dr. Ajit S Mullasari: Conception of trial design and provided the  
50 important intellectual content  
51

52 Dr. Suma M Victor: Drafting of the article  
53

54 Dr. Ganesh Veerasekar: Drafting of tables and Images  
55

56 Dr. Kala Subramaniam: Provided the statistical design  
57  
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3 Dr. Brahmajee K Nallamothe: Final correction & approval of the version  
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8 **Disclosures:**  
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10 This study is funded by 'STEMI India'. This study has been accepted by Indian Council of  
11  
12 Medical Research and is still awaiting release of funds.  
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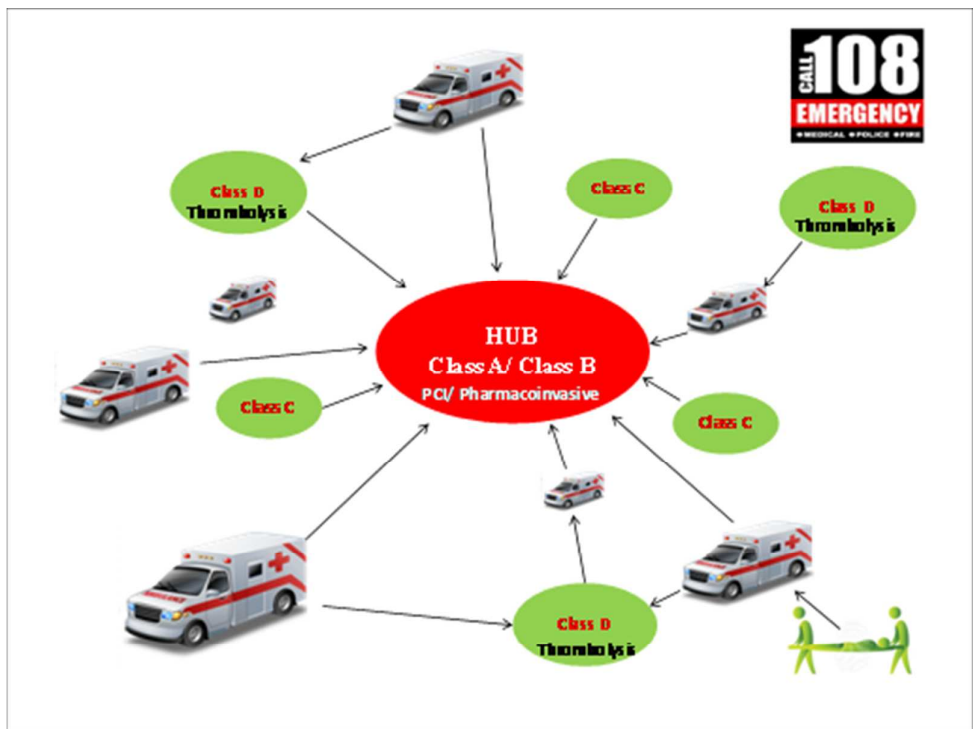
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15 Conflict of interests: The author(s) declare that they have no conflicting interests.  
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<b>CLUSTER 1:</b>		
<b>HUB HOSPITAL</b>	<b>SPOKE HOSPITAL</b>	<b>CLASS</b>
Kovai Medical Centre & Hospital, Coimbatore (Class A)	The Pollachi Cardiac Centre, Pollachi	Class D
	SAS Clinic Cardiac Centre, Dharapuram	Class D
	Amaravathy Hospital, Karur	Class D
	TMF Hospital, Tirupur	Class D
	Sri Kuppusamy Hospital, Tirupur	Class D
	Ramya Nursing Home, Nambiyur	Class C
	Sri Kumaran Hospital, Tirupur	Class D
	CFH Hospital, Oddanchathiram	Class D
Recently Added	Coimbatore Medical College Hospital	Class D
	Tirupur General Hospital, Tirupur	Class D
	Dharapuram GH	Class D
	Ooty GH	Class D
	Mettupalayam GH	Class C
	Udumalpet GH	Class D
	Pollachi Government Hospital	Class C
<b>CLUSTER 2:</b>		
<b>HUB HOSPITAL</b>	<b>SPOKE HOSPITAL</b>	<b>CLASS</b>
Madras Medical Mission, Chennai (Class A)	Velammal Hospital, Chennai	Class D
	Sundaram Medical Foundation, Chennai	Class D
	Dr. Mohan's Diabetes Specialities Centre, Chennai	Class D
Proposed Hospitals		
	Thiruvanmayur Government Hospital, Thiruvanmayur	Class D
	Kanchipuram Government Hospital,	Class D

	Kanchipuram	
<b>CLUSTER 3:</b>		
<b>HUB HOSPITAL</b>	<b>SPOKE HOSPITAL</b>	<b>CLASS</b>
Christian Medical College, Vellore (Class A)	LCECU Hospital, Vellore	Class C
	Narayani Hospital & Research Centre, Vellore	Class D
	Scudder Memorial Hospital, Ranipet	Class D
	Rusha Hospital, Vellore	Class D
	CHAD Hospital, Vellore	Class D
	S.L.R. & T.C. Hospital, Karigiri	Class D
	Bethesda Hospital, Ambur	Class D
Proposed Hospitals		
	Vellore Medical College Hospital, Vellore	Class D
<b>CLUSTER 4:</b>		
<b>HUB HOSPITAL</b>	<b>SPOKE HOSPITAL</b>	<b>CLASS</b>
Stanley Medical College, Chennai(Class A)	Government Hospital Thiruvallur.	Class D
	Kilpauk Medical College Chennai.	Class D
	Primary Health Center, Gummidipundi.	Class C
	Government Hospital Chengalpet.	Class D
	Proposed Hospitals	
	All approved private hospitals around Stanley Hospitals, Chennai	Class C/D

## Appendix:

Table 1: Provision of software to STEMI team

STEMI Software	Paramedic	STEMI coordinator	On- Call Cardiologist	STEMI coordinating Centre
Hand held device	Android 4.0 – ‘Ice Cream Sandwich’ , 2G or 3G connectivity	Android 4.0 – ‘Ice Cream Sandwich’ , 2G or 3G connectivity	Samsung Galaxy Tab 2 P 310, 2G or 3G connectivity	-
ECG Device/Monitor	connected via USB cable to the hand held device	-	-	-
Transmitting device	Intel® Atom™ processor N450 at 1.66G Hz	Intel® Atom™ processor N450 at 1.66G Hz	-	-
Data Server	-	-	-	Hosted application: Windows 2008 R2 Standard, SQL Server 2008 R2 Standard Edition

**Table 2: ECG signal specifications:**

Electrodes / leads	Standard 10 lead patient cable / 12lead ECG
Frequency response	0.05 to 125 Hz
Leakage current	< 10 micro amps
CMRR	> 100 dB
Input impedance	> 4 M ohms
Filter	To suppress supply frequency fluctuations
A/D conversion resolution	12 bit
Sampling rate	500 samples/sec
Defibrillator protection	Pulse characteristics of 5kV potential , pulse duration (5 to 20 ms), carrying energy of 360 joules

**Table 3: Arterial saturation (SaO<sub>2</sub>) signal specification:**

Method	Pulse oximetry with finger clip sensors
Range	0-100%
Accuracy	SaO <sub>2</sub> > 70% +/- 2% Pulse rate: +/- 2 bpm
Time required for calculation	<10 seconds
Refresh rate	10 seconds

**Table 4: Blood pressure (BP) signal specification:**

Operating mode	Non-supervised continuous operation
Type of measurement	Oscillometric
Pressure range	0-300 mmHg
Pressure accuracy	±3 mmHg
Measurement ranges for adults – Systolic BP Diastolic BP Mean arterial BP	25 - 280 mmHg 10 - 220 mmHg 15 - 260 mmHg
Air leakage rate of the system	< 3 mmHg / minute
Time required for BP measurement	within 30 seconds, and upto maximum of 90 seconds.

**Table 5: Battery details**

Type	Rechargeable Lithium Ion 7.4V – 4000 mA
Typical working hours	Upto 6 hours of backup
Charging time	8 hours for full charge in standard charging mode
Indicator	Charging and full charge indicator

**Table 6: Display Device Specifications**

(Make : Connoi SmartBook Convertible ST10160)

Processor/chipset	Intel® Atom™ processor N450 at 1.66G Hz Chipset: Intel® NM10 Express
Memory	1GB / 2GB
Storage Device	2.5" SATA HDD (Supports 32G/16G/8G SATA Flash)
Operating System	Android 4.0
LCD	10.1" 1024 x 600 water resistant touch screen <ul style="list-style-type: none"> <li>• 10.1" 1366x768 optional display</li> <li>• Convertible: traditional or touch-optimized tablet mode</li> <li>• Palm-resting feature allows to write and draw comfortably</li> </ul>
Connectivity	10M/100M Ethernet 802.11b/g/n WLAN <ul style="list-style-type: none"> <li>• 3G</li> <li>• GPS</li> </ul>
Keyboard/touch Pad	<ul style="list-style-type: none"> <li>• Water resistant keyboard</li> <li>• Water resistant touch pad (integrated vertical scrolling)</li> <li>• Anti-microbial keyboard</li> </ul>
Battery	4-cell battery (4.8 hrs) (2200mAh cell)
System I/O	2 x USB 2.0 ports, 1 SD slot, VGA port ,1 half sized mini-card slot and 1 full sized mini-card slot, dual audio jacks
Built-in 1.3MPX rotating Camera	30fps (640 x 480) 1.3MP rotatable
Accelerometer	Tilt the Intel-powered convertible classmate PC and the display switches smoothly from portrait to landscape HDD Protection
Handle	Integrated retractable handle to support micro-mobility
Custom Mini-Chassis	<ul style="list-style-type: none"> <li>• Size including handle: 268mm x (39.5~32mm)</li> </ul>

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	x 214mm • Weight: 1.52–1.74Kg
Drop Test	Flash 70cm/HDD 60cm

**Table 7: Carry case specifications**

Weight	< 4.5 Kg
Carry case size	330 mm x 210 mm x 110 mm
Material	Industrial grade ABS

For peer review only



Protocol No: LA-RSH/103/2012	Site ID: <table border="1" style="display: inline-table; border-collapse: collapse; text-align: center;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;">-</td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;">-</td> <td style="width: 20px; height: 20px;"></td> </tr> </table>			-			-	
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	Patient ID: _____							

**Case Report Form (Baseline Data Collection)  
Class A/B Hospital**

**A prospective, controlled study of assertive and timely reperfusion for patients with ST-segment elevation myocardial infarction (STEMI) in Tamil Nadu.**

<b>Protocol No : LA-RSH/103/2012</b>	<b>Protocol Version &amp; Date : Version 2.0, 18-Apr-2012</b>
<b>CRF (Baseline Data Collection) : Version 1.0</b>	<b>Sponsor : STEMI India Group</b>

Treating Hospital	
Name of the Hospital:	
Address :	

Patient Details		Alternate Contact Details	
Name:		Name:	
Telephone No.:		Telephone No.:	
Address :		Address :	

Demography and Personal History		
Date of Visit : ____/____/____ DD MMM YYYY	Age: _____ years	Gender : 1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female
Occupation: _____	Tobacco Smoking Status	1 <input type="checkbox"/> Non Smoker 2 <input type="checkbox"/> Current Smoker 3 <input type="checkbox"/> Past Smoker 4 <input type="checkbox"/> Smoking Status Unknown 5 <input type="checkbox"/> Passive 99 <input type="checkbox"/> Others, please specify _____
If smoking, please provide the details:		
Number: _____	Duration: _____	Type: _____

Protocol No: LA-RSH/103/2012

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Patient ID: \_\_\_\_\_

**Clinical examination**

Height: \_\_\_\_\_ cm

Weight: \_\_\_\_\_ kg

BMI : \_\_\_\_\_ Kg/m<sup>2</sup>Blood Pressure: \_\_\_\_\_ / \_\_\_\_\_ mm of Hg  
Systolic Diastolic

Heart Rate : \_\_\_\_\_ Beats/min

**Diagnosis**

Presenting complaints:

- 1  Chest pain  
 2  Palpitations  
 3  Pain in other locations (Arm pain, Jaw Pain.....)  
 4  Diaphoresis  
 5  Syncope  
 6  Dyspnea  
 99  Others, specify \_\_\_\_\_

**DIRECT ADMISSION** Not Applicable

Date and Time of Arrival at Hospital

\_\_\_\_ / \_\_\_\_ / \_\_\_\_  
DD MMM YYYY\_\_\_\_ : \_\_\_\_  
HH MM NA

Mode of Transportation:

1  Private 2  Public 3  Ambulance 9  Not Applicable

If Ambulance, Please provide the below details:

Ambulance call time: \_\_\_\_ : \_\_\_\_  
HH MMAmbulance arrival time: \_\_\_\_ : \_\_\_\_  
HH MM NA

Date and Time of Symptom Onset:

\_\_\_\_ / \_\_\_\_ / \_\_\_\_  
DD MMM YYYY\_\_\_\_ : \_\_\_\_  
HH MM NA

Initial ECG Time:

\_\_\_\_ : \_\_\_\_  
HH MM NA

Time of STEMI confirmation:

\_\_\_\_ : \_\_\_\_  
HH MM NA

Location of infarction (as per ECG)

Protocol No: LA-RSH/103/2012

Site ID:

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Patient ID: \_\_\_\_\_

<b>DIRECT EMRI TRANSFER</b>	<input type="checkbox"/> Not Applicable		
Date and Time of Call to EMRI	____/____/____ DD MMM YYYY	____:____ HH MM	<input type="checkbox"/> NA
Date and Time of EMRI despatch	____/____/____ DD MMM YYYY	____:____ HH MM	<input type="checkbox"/> NA
Time of arrival at patient site:	____:____ HH MM	<input type="checkbox"/> NA	
Time of departure from scene:	____:____ HH MM	<input type="checkbox"/> NA	
Date and Time of Symptom Onset:	____/____/____ DD MMM YYYY	____:____ HH MM	<input type="checkbox"/> NA
Date and Time of Arrival at Hospital	____/____/____ DD MMM YYYY	____:____ HH MM	<input type="checkbox"/> NA
Location of ECG Recording:	3 <input type="checkbox"/> Ambulance 1 <input type="checkbox"/> Hospital 9 <input type="checkbox"/> Not Applicable		
Initial ECG Time:	____:____ HH MM	<input type="checkbox"/> NA	
Time of STEMI confirmation:	____:____ HH MM	<input type="checkbox"/> NA	
Location of infarction(as per ECG)			

<b>EMRI TRANSFER FROM C/D SPOKE</b>		
Mention the spoke hospital patient has been transferred from:	3 <input type="checkbox"/> Class C 4 <input type="checkbox"/> Class D	
Is the patient accompanied with the Baseline CRF from the spoke hospital:	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	
If yes, has the form been attached to the Class A/B CRF:	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	
Time of arrival in Hospital A/B:	____:____ HH MM	<input type="checkbox"/> NA

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Patient ID: \_\_\_\_\_

<b>NON STEMI CLUSTER ENTRY</b>	<input type="checkbox"/> Not Applicable		
Time of arrival of patient at non STEMI cluster Hospital:	__/__/____ DD MMM YYYY	__:____ HH MM	<input type="checkbox"/> NA
Date and Time of Symptom Onset:	__/__/____ DD MMM YYYY	__:____ HH MM	<input type="checkbox"/> NA
Initial ECG Time:	__:____ HH MM	<input type="checkbox"/> NA	
Time of STEMI confirmation:	__:____ HH MM	<input type="checkbox"/> NA	
Location of infarction (as per ECG)			
Mode of Transportation:	1 <input type="checkbox"/> Private 2 <input type="checkbox"/> Public 3 <input type="checkbox"/> Ambulance 4 <input type="checkbox"/> EMRI 5 <input type="checkbox"/> Not known		
EMRI/Ambulance call time: __:____ HH MM	EMRI/Ambulance arrival time: __:____ HH MM	<input type="checkbox"/> NA	
Time of start of patient transfer:	__:____ HH MM	<input type="checkbox"/> NA	
Time of arrival in Hospital A/B:	__:____ HH MM	<input type="checkbox"/> NA	

Medication at Previous Hospital/ during Transfer					
Was any medication administered to the patient at previous hospital/during transfer?				1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
If Yes, please provide the below details:					
Medication	Route	Dose	Date of Administration (DD/MMM/YYYY)	Time of Administration (HH:MM)	

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Patient ID: \_\_\_\_\_

**Fibrinolytic Checklist**

Sl.No		Responses	
1.	Is Systolic BP greater than 180 mm Hg ?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
2.	Is Diastolic BP greater than 110 mm Hg?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
3.	Is Right vs. left arm systolic BP difference greater than 15 mm Hg ?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
4.	History of structural central nervous system disease ?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
5.	Significant closed head/facial trauma within the previous 3 months ?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
6.	Recent (within 6 wks) major trauma, surgery (including laser eye surgery) GI/GU bleed ?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
7.	Bleeding or clotting problem or on blood thinners?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
8.	CPR greater than 10 minutes?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
9.	Pregnant Female?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
10.	Serious systemic disease (eg. advanced / terminal cancer, severe liver or kidney disease) ?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
11.	Does the patient have severe heart failure or cardiogenic shock such that PCI is preferable?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
12.	Pulmonary edema (rales greater than halfway up)	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
13.	Systemic hypoperfusion (cool, clammy)	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No

**Medication Prior to Thrombolysis**

Medication	Route of Administration	Actual Dosage Administered		Administration	
		Mg	U	DD/MMM/YYYY	HH : MM
<input type="checkbox"/> Aspirin					
<input type="checkbox"/> Clopidogrel					
<input type="checkbox"/> Unfractionated Heparin					
<input type="checkbox"/> Low Molecular Weight Heparin, specify _____					

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Patient ID: \_\_\_\_\_

**Thrombolysis**

Was the subject Thrombolysed:

1  Yes0  No9  Not Applicable

If Yes, Please provide the below details:

Thrombolytic Agent	Route of Administration	Actual Dosage Administered		Start of Thrombolysis		Completion of Thrombolysis	
		Mg	U	DD/MMM/YYYY	HH : MM	DD/MMM/YYYY	HH : MM
<input type="checkbox"/> Streptokinase							
<input type="checkbox"/> Tenectapase							
<input type="checkbox"/> Others, Specify _____							
90-120 min ECG Time:	____:____ HH MM						<input type="checkbox"/> NA

**Medication Prior to PCI**

Medication	Route of Administration	Actual Dosage Administered		Administration	
		Mg	U	DD/MMM/YYYY	HH : MM
<input type="checkbox"/> Aspirin					
<input type="checkbox"/> Clopidogrel					
<input type="checkbox"/> Prasugrel					
<input type="checkbox"/> Unfractionated Heparin					
<input type="checkbox"/> Low Molecular Weight Heparin, specify _____					

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Patient ID: \_\_\_\_\_

**PCI**

Cath Lab activation time:	____:____ HH MM	<input type="checkbox"/> NA			
Patient Arrival Time at Cath Lab	____:____ HH MM	<input type="checkbox"/> NA			
Date and Time of Vascular Access:	____/____/____ DD MMM YYYY	____:____ HH MM			
Date and Time of Start of Diagnostic Angiography:	____/____/____ DD MMM YYYY	____:____ HH MM			
Date and Time of End of Diagnostic Angiography:	____/____/____ DD MMM YYYY	____:____ HH MM			
Catheter Access:	1 <input type="checkbox"/> Radial	2 <input type="checkbox"/> Femoral			
Findings of Diagnostic Angiography:	1 <input type="checkbox"/> Single Vessel Disease	2 <input type="checkbox"/> Double Vessel			
	3 <input type="checkbox"/> Triple Vessel Disease	4 <input type="checkbox"/> Insignificant Disease			
Aspiration	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No				
Date and Time of Balloon Inflation/Stent deployment:	____/____/____ DD MMM YYYY	____:____ HH MM			
<b>Vessels</b>	<b>Stenosis?</b>	<b>Severity</b>	<b>Culprit Vessel</b>	<b>No. of Stents</b>	<b>Type of Stent</b>
<input type="checkbox"/> Left Anterior Descending (LAD)	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	____%	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No		1 <input type="checkbox"/> DES 2 <input type="checkbox"/> BMS 3 <input type="checkbox"/> M Gaurd
<input type="checkbox"/> Left Circumflex Artery (LCX)	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	____%	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No		1 <input type="checkbox"/> DES 2 <input type="checkbox"/> BMS 3 <input type="checkbox"/> M Gaurd
<input type="checkbox"/> Right Coronary Artery (RCA)	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	____%	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No		1 <input type="checkbox"/> DES 2 <input type="checkbox"/> BMS 3 <input type="checkbox"/> M Gaurd
<input type="checkbox"/> Others, Specify _____	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	____%	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No		1 <input type="checkbox"/> DES 2 <input type="checkbox"/> BMS 3 <input type="checkbox"/> M Gaurd

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Patient ID: \_\_\_\_\_

**Medication in Cath Lab**

Medication	Route of Administration	Actual Dosage Administered		Administration	
		Mg	U	DD/MMM/YYYY	HH : MM
<input type="checkbox"/> Aspirin					
<input type="checkbox"/> Clopidogrel					
<input type="checkbox"/> Prasugrel					
<input type="checkbox"/> Unfractionated Heparin					
<input type="checkbox"/> Low Molecular Weight Heparin, specify _____					
GP IIb/IIIa Inhibitors					
<input type="checkbox"/> Abciximab					
<input type="checkbox"/> Eptifibatide					
<input type="checkbox"/> Tirofiban					
<input type="checkbox"/> Others					
Specify: _____					
<input type="checkbox"/> Bivaluridin					
<input type="checkbox"/> Fondoparinux					



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Patient ID: \_\_\_\_\_

**Other Medication During Hospitalization**

Was any other medication administered to the patient during hospitalization in Hospital A/B? 1  Yes 0  No

If Yes, please provide the below details:

Medication	Route	Dose	Date of Administration (DD/MMM/YYYY)	Time of Administration (HH:MM)

**Discharge Summary**

Date of Discharge: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
DD MMM YYYY

Recommendations:  
 1  Conservative Treatment  
 2  Referred to Class A/B hospital  
 3  Non STEMI Cluster hospital  
 99  Others, Specify \_\_\_\_\_

Protocol No: LA-RSH/103/2012

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Patient ID: \_\_\_\_\_

**Medication on Discharge**

Was the Patient prescribed any medication on discharge?

1  Yes    0  No

If Yes, provide the details below:

SI No.	Medication Name

**Adverse Events**

Adverse event experienced?:

1  Yes    0  No

If Yes, provide the below details:

SI #	Adverse Event	Response	Comments
1	Stroke	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
2	Cardiogenic Shock	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
3	Access site Hemorrhage	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
4	Major Bleed <sup>#</sup>	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
5	Minor Bleed <sup>#</sup>	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
6	Death <input type="checkbox"/> Cardiac <input type="checkbox"/> Non Cardiac	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
7	Symptomatic Ischemia	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
8	Others Specify _____	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	

#Derived based on TIMI Score Scale

Protocol No: LA-RSH/103/2012

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Patient ID: \_\_\_\_\_

**ADDITIONAL INFORMATION**

**Medical/Surgical History**

Does the subject have any other clinically significant medical /surgical history?  
 If Yes, provide the details below: 1  Yes    0  No

Symptom/Diagnosis/ Procedure <sup>#</sup>	Response	Medication (If Applicable)
Diabetes Mellitus	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
Hypertension	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
Peripheral Vascular Disease	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
Stroke	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
Dyslipidemia	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
Allergies	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
Bronchial Asthma	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
CAD (including Angina and MI)	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
Others, Specify _____	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
_____		

**If the response to Medical History is checked as CAD, please provide previous management details:**

Previous Management	Date	Details
<input type="checkbox"/> Medical Management	___/___/___ DD    MMM    YYYY	
<input type="checkbox"/> PCI	___/___/___ DD    MMM    YYYY	
<input type="checkbox"/> CABG	___/___/___ DD    MMM    YYYY	
<input type="checkbox"/> Others Specify: _____	___/___/___ DD    MMM    YYYY	

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<b>Investigator Comments (if any)</b>
<hr/> <hr/>

<b>Investigator Declaration</b>
<p>I certify that I have reviewed all of the data contained within these case report forms and that it accurately reflects the course of this patient on this study. I understand that changes may be made to this data as a result of the data review process.</p> <p>Investigator Name : _____</p> <p>Investigator Signature : _____</p> <p style="text-align: right; margin-right: 50px;">       ____/____/____        DD    MMM    YYYY     </p>

Protocol No: LA-RSH/103/2012

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Patient ID: \_\_\_\_\_

**Follow up (1 Month)**

Was the subject followed up:	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If followed up, please specify:	1 <input type="checkbox"/> Hospital    2 <input type="checkbox"/> Telephonic Follow up    3 <input type="checkbox"/> Lost to Follow up	
Date of follow up:	____/____/____ DD    MMM    YYYY	
<b>Medical Condition</b>	<b>Response</b>	
Asymptomatic	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Stroke	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Death <input type="checkbox"/> Cardiac <input type="checkbox"/> Non Cardiac	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If the Patient is Dead, please provide the details:	____/____/____ DD    MMM    YYYY	____:____ HH    MM
Re-infarction	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If yes, please provide the details:	____/____/____ DD    MMM    YYYY	____:____ HH    MM
Symptomatic Ischemia	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Cardiac failure	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Repeat Intervention	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If yes, please provide details		
<input type="checkbox"/> CABG	____/____/____ DD    MMM    YYYY	____:____ HH    MM
<input type="checkbox"/> PCI	____/____/____ DD    MMM    YYYY	____:____ HH    MM
<b>Comments (if any)</b>		
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Patient ID: \_\_\_\_\_

**Follow up (6 Month)**

Was the subject followed up:	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If followed up, please specify:	1 <input type="checkbox"/> Hospital    2 <input type="checkbox"/> Telephonic Follow up    3 <input type="checkbox"/> Lost to Follow up	
Date of follow up:	____/____/____ DD    MMM    YYYY	
<b>Medical Condition</b>	<b>Response</b>	
Asymptomatic	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Stroke	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Death <input type="checkbox"/> Cardiac <input type="checkbox"/> Non Cardiac	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If the Patient is Dead, please provide the details:	____/____/____ DD    MMM    YYYY	____:____ HH    MM
Re-infarction	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If yes, please provide the details:	____/____/____ DD    MMM    YYYY	____:____ HH    MM
Symptomatic Ischemia	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Cardiac failure	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Repeat Intervention	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If yes, please provide details		
<input type="checkbox"/> CABG	____/____/____ DD    MMM    YYYY	____:____ HH    MM
<input type="checkbox"/> PCI	____/____/____ DD    MMM    YYYY	____:____ HH    MM
<b>Comments (if any)</b>		
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Patient ID: \_\_\_\_\_

**Follow up (1 Year)**

Was the subject followed up:	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If followed up, please specify:	1 <input type="checkbox"/> Hospital    2 <input type="checkbox"/> Telephonic Follow up    3 <input type="checkbox"/> Lost to Follow up	
Date of follow up:	____/____/____ DD    MMM    YYYY	
<b>Medical Condition</b>	<b>Response</b>	
Asymptomatic	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Stroke	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Death <input type="checkbox"/> Cardiac <input type="checkbox"/> Non Cardiac	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If the Patient is Dead, please provide the details:	____/____/____ DD    MMM    YYYY	____:____ HH        MM
Re-infarction	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If yes, please provide the details:	____/____/____ DD    MMM    YYYY	____:____ HH        MM
Symptomatic Ischemia	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Cardiac failure	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Repeat Intervention	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If yes, please provide details		
<input type="checkbox"/> CABG	____/____/____ DD    MMM    YYYY	____:____ HH        MM
<input type="checkbox"/> PCI	____/____/____ DD    MMM    YYYY	____:____ HH        MM
<b>Comments (if any)</b>		
_____		
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Patient ID: \_\_\_\_\_

**Case Report Form (Baseline Data Collection)  
Class C Hospital –Direct Admission**

**A prospective, controlled study of assertive and timely reperfusion for patients with ST-segment elevation myocardial infarction (STEMI) in Tamil Nadu.**

<b>Protocol No : LA-RSH/103/2012</b>	<b>Protocol Version &amp; Date : Version 2.0, 18-Apr-2012</b>
<b>CRF (Baseline Data Collection) : Version 1.0</b>	<b>Sponsor : STEMI India Group</b>

Treating Hospital	
Name of the Hospital:	
Address :	

Patient Details		Alternate Contact Details	
Name:		Name:	
Telephone No.:		Telephone No.:	
Address :		Address :	

Demography and Personal History		
Date of Visit : ____/____/____ DD MMM YYYY	Age: ____ years	Gender : 1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female
Occupation: _____	Tobacco Smoking Status	1 <input type="checkbox"/> Non Smoker 2 <input type="checkbox"/> Current Smoker 3 <input type="checkbox"/> Past Smoker 4 <input type="checkbox"/> Smoking Status Unknown 5 <input type="checkbox"/> Passive 99 <input type="checkbox"/> Others, please specify _____
If smoking, please provide the details:		
Number: _____	Duration: _____	Type: _____



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		-			-	C		
	Patient ID: _____							

Clinical examination		
Height: _____ cm	Weight: _____ kg	BMI : _____ Kg/m <sup>2</sup>
Blood Pressure: _____ / _____ mm of Hg <div style="text-align: center; margin-top: 5px;"> <span style="margin-right: 40px;">Systolic</span> <span>Diastolic</span> </div>	Heart Rate : _____ Beats/min	

Diagnosis		
Presenting complaints:	1 <input type="checkbox"/> Chest pain 2 <input type="checkbox"/> Palpitations 3 <input type="checkbox"/> Pain in other locations (Arm pain, Jaw Pain.....) 4 <input type="checkbox"/> Diaphoresis 5 <input type="checkbox"/> Syncope 6 <input type="checkbox"/> Dyspnea 99 <input type="checkbox"/> Others, specify _____	
Date and Time of Arrival at Hospital	____ / ____ / ____ DD    MMM    YYYY	____ : ____ HH    MM
Mode of Transportation:	1 <input type="checkbox"/> Private      2 <input type="checkbox"/> Public      3 <input type="checkbox"/> Ambulance	
If Ambulance, Please provide the below details:		
Ambulance call time: ____ : ____ <div style="text-align: center; margin-top: 5px;"> <span style="margin-right: 40px;">HH</span> <span>MM</span> </div>	Ambulance arrival time: ____ : ____ <div style="text-align: center; margin-top: 5px;"> <span style="margin-right: 40px;">HH</span> <span>MM</span> </div>	
Date and Time of Onset of Symptom:	____ / ____ / ____ DD    MMM    YYYY	____ : ____ HH    MM
Date and Time of FMC:	____ / ____ / ____ DD    MMM    YYYY	____ : ____ HH    MM
Initia ECG Time:	____ : ____ HH    MM	
Time of STEMI confirmation:	____ : ____ HH    MM	
Location of infarction(as per ECG)		

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Patient ID: \_\_\_\_\_

### Medication During Hospitalization

Was any other medication administered to the patient during hospitalization? 1  Yes 0  No

If Yes, please provide the below details:

Medication	Route	Dose	Date of Administration (DD/MMM/YYYY)	Time of Administration (HH:MM)

### Discharge Summary

Date of Discharge:

\_\_\_/\_\_\_/\_\_\_  
DD MMM YYYY

Recommendations:

- 1  Conservative Treatment  
 2  Referred to Class A/B hospital  
 3  Non STEMI Cluster hospital  
 99  Others, Specify \_\_\_\_\_

### Medication on Discharge

Was the Patient prescribed any medication on discharge?

1  Yes 0  No

If Yes, provide the details below:

SI No.	Medication Name

Protocol No: LA-RSH/103/2012	Site ID: <table border="1" style="display: inline-table; border-collapse: collapse; text-align: center;"> <tr> <td style="width: 20px; height: 20px;"> </td> <td style="width: 20px; height: 20px;"> </td> <td style="width: 20px; height: 20px;">-</td> <td style="width: 20px; height: 20px;"> </td> <td style="width: 20px; height: 20px;"> </td> <td style="width: 20px; height: 20px;">-</td> <td style="width: 20px; height: 20px;">C</td> </tr> </table>			-			-	C
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	Patient ID: _____							

**Referral Hospital**

Type of Referral hospital notified:	1 <input type="checkbox"/> Class A	2 <input type="checkbox"/> Class B	99 <input type="checkbox"/> Others, Specify _____ _____
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Details of Referral Hospital:	Name: _____		
	Address: _____		

Date and Time of notification to Referral Hospital	____/____/____ DD    MMM    YYYY	____:____ HH    MM
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Mode of Transportaion to Referral Hospital:	1 <input type="checkbox"/> Private	3 <input type="checkbox"/> Ambulance	4 <input type="checkbox"/> EMRI
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If EMRI or Ambulance, provide the below details:

Call Time:	____:____ HH    MM
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Arrival Time:	____:____ HH    MM
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Transport Start Time:	____:____ HH    MM
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**Management at Referral Hospital**

1 <input type="checkbox"/> PCI
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2 <input type="checkbox"/> Medical Management
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3 <input type="checkbox"/> Unknown
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99 <input type="checkbox"/> Others, Specify _____
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Protocol No: LA-RSH/103/2012

Site ID:

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Patient ID: \_\_\_\_\_

**Adverse Events**

Adverse event experienced?: 1  Yes 0  No

If Yes, provide the below details:

SI #	Adverse Event	Response	Comments
1	Stroke	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	
2	Cardiogenic Shock	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	
3	Access site Hemorrhage	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	
4	Major Bleed <sup>#</sup>	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	
5	Minor Bleed <sup>#</sup>	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	
6	Death <input type="checkbox"/> Cardiac <input type="checkbox"/> Non Cardiac	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	
7	Symptomatic Ischemia	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	
8	<u>Others Specify</u>	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No	

#derived based on TIMI Score Scale

Protocol No: LA-RSH/103/2012

Site ID:

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Patient ID: \_\_\_\_\_

**ADDITIONAL INFORMATION**

**Medical/Surgical History**

Does the subject have any other clinically significant medical /surgical history? 1  Yes    0  No

If Yes, provide the details below:

Symptom/Diagnosis/ Procedure <sup>#</sup>	Response	Medication (If Applicable)
Diabetes Mellitus	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
Hypertension	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
Peripheral Vascular Disease	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
Stroke	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
Dyslipidemia	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
Allergies	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
Bronchial Asthma	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
CAD (including Angina and MI)	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
Others, Specify _____	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
_____		

**If the response to Medical History is checked as CAD, please provide previous management details:**

Previous Management	Date	Details
<input type="checkbox"/> Medical Management	___ / ___ / ___ DD    MMM    YYYY	
<input type="checkbox"/> PCI	___ / ___ / ___ DD    MMM    YYYY	
<input type="checkbox"/> CABG	___ / ___ / ___ DD    MMM    YYYY	
<input type="checkbox"/> Others Specify: _____	___ / ___ / ___ DD    MMM    YYYY	

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Protocol No: LA-RSH/103/2012	Site ID: <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">-</td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px; text-align: center;">-</td> <td style="width: 20px; height: 20px; text-align: center;">C</td> </tr> </table> Patient ID: _____			-			-	C
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<b>Investigator Comments</b>
<hr style="border: 0; border-top: 1px solid black; margin-bottom: 10px;"/> <hr style="border: 0; border-top: 1px solid black;"/>

<b>Investigator Declaration</b>
<p>I certify that I have reviewed all of the data contained within these case report forms and that it accurately reflects the course of this patient on this study. I understand that changes may be made to this data as a result of the data review process.</p> <p>Investigator Name : _____</p> <p>Investigator Signature : _____</p> <div style="text-align: right; margin-top: 10px;">       ____/____/____        DD    MMM    YYYY     </div>

Peer review only

Protocol No: LA-RSH/103/2012

Site ID:

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Patient ID: \_\_\_\_\_

**Case Report Form (Baseline Data Collection)  
Class D Hospital –Direct Admission/EMRI Transfer**

**A prospective, controlled study of assertive and timely reperfusion for patients with ST-segment elevation myocardial infarction (STEMI) in Tamil Nadu.**

<b>Protocol No : LA-RSH/103/2012</b>	<b>Protocol Version &amp; Date : Version 2.0, 18-Apr-2012</b>
<b>CRF (Baseline Data Collection) : Version 1.0</b>	<b>Sponsor : STEMI India Group</b>

Treating Hospital	
Name of the Hospital:	
Address :	

Patient Details		Alternate Contact Details	
Name:		Name:	
Telephone No.:		Telephone No.:	
Address :		Address :	

Demography and Personal History		
Date of Visit : ____/____/____ DD MMM YYYY	Age: ____years	Gender : 1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female
Occupation: _____	Tobacco Smoking Status	1 <input type="checkbox"/> Non Smoker 2 <input type="checkbox"/> Current Smoker 3 <input type="checkbox"/> Past Smoker 4 <input type="checkbox"/> Smoking Status Unknown 5 <input type="checkbox"/> Passive 99 <input type="checkbox"/> Others, please specify _____
If smoking, please provide the details:		
Number: _____	Duration: _____	Type: _____

Protocol No: LA-RSH/103/2012

Site ID:

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Patient ID: \_\_\_\_\_

**Clinical examination**

Height: \_\_\_\_\_ cm

Weight: \_\_\_\_\_ kg

BMI : \_\_\_\_\_ Kg/m<sup>2</sup>Blood Pressure: \_\_\_\_\_ / \_\_\_\_\_ mm of Hg  
Systolic Diastolic

Heart Rate : \_\_\_\_\_ Beats/min

**Patient admission to hospital:**1  Direct Admission 2  Direct EMRI Transfer 3  Referring Hospital/Clinic

If the Patient admission was through Direct EMRI Transfer, please fill the below details:

**EMRI**

Date and Time of Call to EMRI

\_\_\_\_/\_\_\_\_/\_\_\_\_  
DD MMM YYYY\_\_\_\_:\_\_\_\_  
HH MM Not available

Date and Time of EMRI despatch

\_\_\_\_/\_\_\_\_/\_\_\_\_  
DD MMM YYYY\_\_\_\_:\_\_\_\_  
HH MM Not available

Time of Arrival at Patient site:

\_\_\_\_:\_\_\_\_  
HH MM Not available

Time of departure from scene:

\_\_\_\_:\_\_\_\_  
HH MM Not available**Diagnosis**

Presenting complaints:

1  Chest pain  
2  Palpitations  
3  Pain in other locations (Arm pain, Jaw Pain.....)4  Diaphoresis  
5  Syncope  
6  Dyspnea  
99  Others, specify \_\_\_\_\_

Date and Time of Arrival at Hospital

\_\_\_\_/\_\_\_\_/\_\_\_\_  
DD MMM YYYY\_\_\_\_:\_\_\_\_  
HH MM Not available

Mode of Transportation:

1  Private 2  Public 3  Ambulance 9  Not Applicable

If Ambulance, Please provide the below details:

Ambulance call time: \_\_\_\_:\_\_\_\_  
HH MMAmbulance arrival time: \_\_\_\_:\_\_\_\_  
HH MM Not available

Date and Time of Symptom Onset:

\_\_\_\_/\_\_\_\_/\_\_\_\_  
DD MMM YYYY\_\_\_\_:\_\_\_\_  
HH MM NA

Location of ECG Recording:

3  Ambulance 1  Hospital 2  Referring Hospital/Clinic  
9  Not Applicable

Initial ECG Time:

\_\_\_\_:\_\_\_\_  
HH MM Not available

Time of STEMI confirmation:

\_\_\_\_:\_\_\_\_  
HH MM Not available

Location of infarction (as per ECG)



Protocol No: LA-RSH/103/2012

Site ID:

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Patient ID: \_\_\_\_\_

**Medication at Previous Hospital/ During Transfer**

Was any medication administered to the patient at previous hospital/during transfer?

1  Yes      0  No

If Yes, please provide the below details:

Medication	Route	Dose	Date of Administration (DD/MM/YYYY)	Time of Administration (HH:MM)

**Fibrinolytic Checklist**

Sl.No		Responses	
1.	Is Systolic BP greater than 180 mm Hg ?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
2.	Is Diastolic BP greater than 110 mm Hg?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
3.	Is Right vs. left arm systolic BP difference greater than 15 mm Hg ?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
4.	History of structural central nervous system disease ?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
5.	Significant closed head/facial trauma within the previous 3 months ?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
6.	Recent (within 6 wks) major trauma, surgery (including laser eye surgery) GI/GU bleed ?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
7.	Bleeding or clotting problem or on blood thinners?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
8.	CPR greater than 10 minutes?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
9.	Pregnant Female?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
10.	Serious systemic disease (eg. advanced / terminal cancer, severe liver or kidney disease) ?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
11.	Does the patient have severe heart failure or cardiogenic shock such that PCI is preferable?	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
12.	Pulmonary edema (rales greater than halfway up)	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No
13.	Systemic hypoperfusion (cool, clammy)	1 <input type="checkbox"/> Yes	0 <input type="checkbox"/> No

Protocol No: LA-RSH/103/2012

Site ID:

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Patient ID: \_\_\_\_\_

### Medication Prior to Thrombolysis

Medication	Route of Administration	Actual Dosage Administered		Administration	
		Mg	U	DD/MMM/YYYY	HH : MM
<input type="checkbox"/> Aspirin					
<input type="checkbox"/> Clopidogrel					
<input type="checkbox"/> Unfractionated Heparin					
<input type="checkbox"/> Low Molecular Weight Heparin, specify _____					

### Thrombolysis

Was the subject Thrombolysed:		1 <input type="checkbox"/> Yes		0 <input type="checkbox"/> No			
If Yes, Please provide the below details:							
Thrombolytic Agent	Route of Administration	Actual Dosage Administered		Start of Thrombolysis		Completion of Thrombolysis	
		Mg	U	DD/MMM/YYYY	HH : MM	DD/MMM/YYYY	HH : MM
<input type="checkbox"/> Streptokinase							
<input type="checkbox"/> Tenectapase							
<input type="checkbox"/> Others, Specify _____							
90-120 min ECG Time:	_____:_____ HH MM			<input type="checkbox"/> NA			

Protocol No: LA-RSH/103/2012

Site ID:

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Patient ID: \_\_\_\_\_

**Other Medication During Hospitalization**

Was any other medication administered to the patient during hospitalization?  Yes  No

If Yes, please provide the below details:

Medication	Route	Dose	Date of Administration (DD/MMM/YYYY)	Time of Administration (HH:MM)

**Discharge Summary**

Date of Discharge: \_\_\_\_\_  
DD MMM YYYY

Recommendations:  Conservative Treatment  
 Referred to Class A/B hospital  
 Non STEMI Cluster hospital  
 Others, Specify \_\_\_\_\_

Protocol No: LA-RSH/103/2012

Site ID:

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Patient ID: \_\_\_\_\_

**Medication on Discharge**

Was the Patient prescribed any medication on discharge?

1  Yes    0  No

If Yes, provide the details below:

SI No.	Medication Name

**Adverse Events**

Adverse event experienced?:

1  Yes    0  No

If Yes, provide the below details:

SI #	Adverse Event	Response	Comments
1	Stroke	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
2	Cardiogenic Shock	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
3	Access site Hemorrhage	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
4	Major Bleed <sup>#</sup>	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
5	Minor Bleed <sup>#</sup>	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
6	Death <input type="checkbox"/> Cardiac <input type="checkbox"/> Non Cardiac	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
7	Symptomatic Ischemia	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
8	Others Specify _____	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	

#Derived based on TIMI Score Scale

Protocol No: LA-RSH/103/2012

Site ID:

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Patient ID: \_\_\_\_\_

**Referral Hospital**

Type of hospital referred :	1 <input type="checkbox"/> STEMI Cluster hospital		2 <input type="checkbox"/> Non STEMI Cluster hospital	
If STEMI Cluster please specify:	1 <input type="checkbox"/> Class A		2 <input type="checkbox"/> Class B	
Details of Referral Hospital:	Name:			
	Address:			
Date and Time of notification to Referral Hospital	____/____/____ DD MMM YYYY		____:____ HH MM	
	<input type="checkbox"/> Not available			
Mode of Transportaion to Referral Hospital:	1 <input type="checkbox"/> Private	3 <input type="checkbox"/> Ambulance	4 <input type="checkbox"/> EMRI	5 <input type="checkbox"/> Not known
If EMRI or Ambulance, provide the below details:				
Call Time:	____:____ HH MM		<input type="checkbox"/> Not available	
Arrival Time:	____:____ HH MM		<input type="checkbox"/> Not available	
Transport Start Time:	____:____ HH MM		<input type="checkbox"/> Not available	
<b>Management at Referral Hospital</b>				
1 <input type="checkbox"/> PCI				
2 <input type="checkbox"/> Medical Management				
3 <input type="checkbox"/> Unknown				
99 <input type="checkbox"/> Others, Specify _____				

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Protocol No: LA-RSH/103/2012

Site ID: 

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Patient ID: \_\_\_\_\_

**ADDITIONAL INFORMATION**

**Medical/Surgical History**

Does the subject have any other clinically significant medical /surgical history?  
 If Yes, provide the details below: 1  Yes    0  No

Symptom/Diagnosis/ Procedure <sup>#</sup>	Response	Medication (If Applicable)
Diabetes Mellitus	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
Hypertension	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
Peripheral Vascular Disease	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
Stroke	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
Dyslipidemia	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
Allergies	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
Bronchial Asthma	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
CAD (including Angina and MI)	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
Others, Specify _____	1 <input type="checkbox"/> Yes    0 <input type="checkbox"/> No	
_____		

**If the response to Medical History is checked as CAD, please provide previous management details:**

Previous Management	Date	Details
<input type="checkbox"/> Medical Management	____/____/____ DD    MMM    YYYY	
<input type="checkbox"/> PCI	____/____/____ DD    MMM    YYYY	
<input type="checkbox"/> CABG	____/____/____ DD    MMM    YYYY	
<input type="checkbox"/> Others Specify: _____	____/____/____ DD    MMM    YYYY	

Protocol No: LA-RSH/103/2012

Site ID:

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Patient ID: \_\_\_\_\_

**Investigator Comments (if any)**

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**Investigator Declaration**

I certify that I have reviewed all of the data contained within these case report forms and that it accurately reflects the course of this patient on this study. I understand that changes may be made to this data as a result of the data review process.

Investigator Name : \_\_\_\_\_

Investigator Signature : \_\_\_\_\_ / \_\_\_\_ / \_\_\_\_  
DD MMM YYYY

For peer review only

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Protocol No: LA-RSH/103/2012

Site ID:

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Patient ID: \_\_\_\_\_

**Follow up (1 Month)**

Was the subject followed up:	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If followed up, please specify:	1 <input type="checkbox"/> Hospital    2 <input type="checkbox"/> Telephonic Follow up    3 <input type="checkbox"/> Lost to Follow up	
Date of follow up:	____/____/____ DD    MMM    YYYY	
<b>Medical Condition</b>	<b>Response</b>	
Asymptomatic	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Stroke	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Death <input type="checkbox"/> Cardiac <input type="checkbox"/> Non Cardiac	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If the Patient is Dead, please provide the details:	____/____/____ DD    MMM    YYYY	____:____ HH    MM
Re-infarction	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If yes, please provide the details:	____/____/____ DD    MMM    YYYY	____:____ HH    MM
Symptomatic Ischemia	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Cardiac failure	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Repeat Intervention	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If yes, please provide details		
<input type="checkbox"/> CABG	____/____/____ DD    MMM    YYYY	____:____ HH    MM
<input type="checkbox"/> PCI	____/____/____ DD    MMM    YYYY	____:____ HH    MM
<b>Comments (if any)</b>		
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_____		



Protocol No: LA-RSH/103/2012

Site ID:

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Patient ID: \_\_\_\_\_

**Follow up (6 Month)**

Was the subject followed up:	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If followed up, please specify:	1 <input type="checkbox"/> Hospital    2 <input type="checkbox"/> Telephonic Follow up    3 <input type="checkbox"/> Lost to Follow up	
Date of follow up:	____/____/____ DD    MMM    YYYY	
<b>Medical Condition</b>	<b>Response</b>	
Asymptomatic	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Stroke	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Death <input type="checkbox"/> Cardiac <input type="checkbox"/> Non Cardiac	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If the Patient is Dead, please provide the details:	____/____/____ DD    MMM    YYYY	____:____ HH    MM
Re-infarction	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If yes, please provide the details:	____/____/____ DD    MMM    YYYY	____:____ HH    MM
Symptomatic Ischemia	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Cardiac failure	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Repeat Intervention	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If yes, please provide details		
<input type="checkbox"/> CABG	____/____/____ DD    MMM    YYYY	____:____ HH    MM
<input type="checkbox"/> PCI	____/____/____ DD    MMM    YYYY	____:____ HH    MM
<b>Comments (if any)</b>		
_____		
_____		

Protocol No: LA-RSH/103/2012

Site ID:

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Patient ID: \_\_\_\_\_

**Follow up (1 Year)**

Was the subject followed up:	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If followed up, please specify:	1 <input type="checkbox"/> Hospital    2 <input type="checkbox"/> Telephonic Follow up    3 <input type="checkbox"/> Lost to Follow up	
Date of follow up:	____/____/____ DD    MMM    YYYY	
<b>Medical Condition</b>	<b>Response</b>	
Asymptomatic	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Stroke	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Death <input type="checkbox"/> Cardiac <input type="checkbox"/> Non Cardiac	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If the Patient is Dead, please provide the details:	____/____/____ DD    MMM    YYYY	____:____ HH    MM
Re-infarction	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If yes, please provide the details:	____/____/____ DD    MMM    YYYY	____:____ HH    MM
Symptomatic Ischemia	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Cardiac failure	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
Repeat Intervention	1 <input type="checkbox"/> Yes      0 <input type="checkbox"/> No	
If yes, please provide details		
<input type="checkbox"/> CABG	____/____/____ DD    MMM    YYYY	____:____ HH    MM
<input type="checkbox"/> PCI	____/____/____ DD    MMM    YYYY	____:____ HH    MM
<b>Comments (if any)</b>		
_____		
_____		