EudraCT Number: 2014-004486-25
Sponsor's Protocol Code Number: GSH2014
National Competent Authority: Italy - Italian Medicines Agency
Clinical Trial Type: EEA CTA
Trial Status: submitted data of the pilot study. The trial is ongoing.
Date on which this record was first entered in the EudraCT database: 2014-12-04
Link: https://www.clinicaltrialsregister.eu/ctr-search/trial/2014-004486-25/IT/

A. Protocol Information
Member State Concerned: Italy - Italian Medicines Agency
EudraCT number: 2014-004486-25
Full title of the trial: Prevention of the reperfusion myocardical damage in patients with acute myocardial infarct (STEMI) submitted to primary PCI through infusion of intravenous glutathione.
Sponsor's protocol code number: GSH2014

B. Sponsor Information
Sponsor 1: University Hospital "Policlinico Umberto I"
Name of organization providing support: University Hospital "Policlinico Umberto I", Rome, Italy.
Functional name of contact point: Enrico Mangieri, University Hospital "Policlinico Umberto I".
Viale del Policlinico, 155 – Rome, Post code: 00161, Italy
E-mail: enrico.mangieri@uniroma1.it

D. IMP Identification
IMP to be used in the trial has a marketing authorisation: Yes
Trade name: TAD
Name of the Marketing Authorisation holder: Biomedica Foscama Group S.p.A.
Country which granted the Marketing Authorisation: Italy
Pharmaceutical form: Powder and solvent for solution for infusion
Routes of administration for this IMP: Intravenous use
Information on Placebo
Pharmaceutical form of the placebo: saline solution
Route of administration of the placebo: Intravenous use

E. General Information on the Trial
Medical condition or disease under investigation
Medical condition(s) being investigated: ST-Segment Elevation Myocardial Infarction (STEMI).
Medical condition in easily understood language: acute myocardial infarct
Therapeutic area: Diseases [C] - Cardiovascular Diseases [C14]
Objective of the trial
Main objective of the trial: To verify if the intravenous infusion of "Glutathione Sodium Salt" it is able to reduce the level of oxidative state in the area of myocardial infarction.
Secondary objectives of the trial: To verify if the intravenous infusion of "Glutathione Sodium Salt" during the procedures of primary PCI it is able to limit the extension of the ischemic area, to reduce the incidence of the no-reflow, to improve the degree of myocardial blush and to decrease the indexes of suffering post-procedural ischemia (ST elevation; release of myocardial necrosis markers).
Principal inclusion criteria: STEMI patients submitted to p-PCI up to 12 hours.
Age≥18 years. Women and Men. Signed informed consent

Principal exclusion criteria:
Patients with cardiac arrest, ventricular fibrillation, cardiogenic shock, stent thrombosis, previous acute myocardial infarction, or angina within 48 hours before infarction were not included in the study. Patients with evidence of coronary collaterals (2-3 Rentrop) to the region at risk on initial coronary angiography (at the time of admission) will be excluded. Moreover, patients with EF ≤30%, impaired renal function (creatinine > 3.0 mg/dl), recipient of heart transplant, a life expectancy less than 12 months, has known allergies to aspirin, clopidogrel bisulfate, heparin, contrast media or stainless steel that cannot be managed medically were excluded.
Patient needs therapy with warfarin or currently participating in an investigational drug or another device study were not considered enrolling.

End points
Primary end point(s): The primary endopoint will consist in the assessment of the effects of the infusion of "Glutathione Sodium Salt" on the reduction of the oxidative markers and inflammation after PCI.
Timepoint(s) of clinical evaluation of this end point: before, 2 hour and 5 days from the p-PCI

Secondary end point(s): The secondary endpoint will include: (1) the assessment of the variations of the corrected TIMI frame count (cTFC) and the TIMI Myocardial Perfusion Grade (TMPG) after p-PCI; (2) the assessment of the middle values of peak of the cardiac Troponin, after the procedure; (3) to verify, through telephone contact or a programmed visit, the principal adverse clinical events as death, acute myocardial infarct, stent's thrombosis of the treated vessels or the occurrence of a new revascularization, up to 6 months after the procedure.
Medical Doctors don't have the knowledge both about the possible infusion of the Glutathione Sodium Salt, in the examined patient, then others clinical data.

Moreover, serological levels of Troponin and creatinine will be measured before the p-PCI and after the procedure (2, 6, 12 and 24 hours).
Besides, through 2D Echocardiography with Simpson's biplane method the FE will be calculate at admission and after hospital discharge.
If clinical-instrumental signs of ischemia will rise up, the patient will be submitted to a new angiography.

Definition of the end of the trial and justification where it is not the last visit of the last subject undergoing the trial: LVLS or telephonic contact
Population of Trial Subjects
Trial has subjects under 18: No
Adults (18-64 years): Yes
Number of subjects for this age range: 30
Elderly (>=65 years): Yes
Number of subjects for this age range: 60
Female: Yes
Male: Yes
Patients: Yes
Specific vulnerable populations: Yes
Women of childbearing potential not using contraception: Yes
Women of child-bearing potential using contraception: Yes

Pregnant women: No
Nursing women: No
Emergency situation: No
Subjects incapable of giving consent personally: No
Planned number of subjects to be included: 90

F. Investigator Networks to be involved in the Trial
N. Review by the Competent Authority or Ethics Committee in the country concerned
N. Competent Authority Decision: Authorised
N. Date of Competent Authority Decision: 2015-01-13
N. Ethics Committee Opinion of the trial application: Favourable
N. Date of Ethics Committee Opinion: 2015-02-12
N. Centers involved in the study: Department of Heart and Great Vessel "A. Reale", Sapienza University of Rome (coordinator centre) - "Santa Maria" Terni Hospital - "San Giovanni Evangelista" Tivoli Hospital, all in Italy.
P. End of Trial Status: analyzed as pilot study the first 50 enrolled patients. Ongoing.