Supplementary file II

Participation Information Sheet and Consent Form

Centre Number: _____ Patient Number: _____

Study Title: COLOR study - Comparative study of complex Percutaneous Coronary Intervention (PCI) procedures with large catheters through the radial artery or femoral artery.

Principle Investigator: Site specific

Name and Address: Site specific
Telephone: Site specific

Sponsor: ISALA Heart Centre, Zwolle, Netherlands.

1. Introduction

We would like to invite you to take part in this study. Participation is voluntary. If you would like to participate, we need your written consent. Before you decide whether to participate in the study or not, you should know what the study entails. Read this information carefully and ask the researcher for an explanation if you have any questions. If you would like more information, you can also consult the independent expert listed at the end of this letter. You can also discuss it with your partner, friends or family.

2. General information

This study was initiated by the cardiology partnership of the Isala hospital in

Zwolle, and is being conducted by multiple cardiologists in the Netherlands, Belgium, Germany, Switzerland and England. The study requires 388 subjects from different countries.

All research is looked at by an independent group of people called Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favorable opinion by the local Ethics Committee.

3. Background of the study

The radial artery (artery in the arm) is smaller than the femoral artery (artery in the leg). Cardiac catheterization and PCI are already often performed through the radial artery. If the PCI procedure required a thicker catheter because the cardiologist needed more sturdiness to complete it, the groin was often used as the access site due to the larger artery. With the development of a thin-walled radial artery sheath, complex PCI procedures with thicker catheters can now also be performed through the radial artery. A complex PCI procedure through the radial artery may lead to fewer access-site complications than through the femoral artery, while providing a similar PCI result, but this has not yet been properly researched.

4. What your participation will entail

If you wish to participate, we will first check whether both the groin and the wrist can be used for the PCI procedure.

Before the procedure, we will ask you questions regarding whether or not you can use your arms and legs properly. We will ask you the same questions again one month after the procedure. You will also be asked to complete 2 questionnaires.

If both the radial and femoral arteries can be used, we will randomly assign you,
- to determine whether you will be treated through the wrist or the groin.

If you are selected for the wrist procedure, we will use the modern sheath. If you are selected for the groin procedure, we will use the standard sheath.

Aside from the potential difference in sheath, the treatment you will receive will be exactly the same as if you did not participate in the study. The procedure may sometimes require the use of a 2nd catheter. In that case, the cardiologist will determine where the access site for the second catheter will be.

The examinations you receive before and after the treatment are also exactly the same as if you did not participate in the study. Those examinations include an electrocardiography (ECG), a blood test and an inspection of the access site (groin or wrist).

The study will require the collection of your medical records for up to one month after the procedure.

5. What is expected of you?
For a good outcome of the study, it is important that you answer the questions during the study visit and the 1-month check-up to the best of your knowledge.

6. Possible complications and other/adverse effects/complaints

In general, the procedure is performed using standard methods and participation in this study will not result in additional adverse effects. The materials used (including the sheaths) have been approved and are already in use for complex PCI procedures for patients who are not participating in a study. The only inconvenience you may experience is that we will contact you after one month to ask you some questions. Trans-Femoral and Trans-radial access will be performed according to the local protocol with the direct needle technique or venous cannula technique. The complications are the same as standard of care procedure and will be fully covered by the Doctor/Investigator during the discussion before consenting to the procedure. Complications that may arise from inserting and removing a sheath are:
-Bleeding
-Vascular problems
-Blood vessel closure

7. Possible advantages and disadvantages

Before you decide to participate in the study, it is important to consider the possible advantages and disadvantages.

If you participate in the study, there is a chance that you will receive exactly the same treatment as if you were not participating. If you are selected for the treatment group with the modern sheath through the wrist, you may have a reduced chance of accesssite complications, but this has not yet been proven. PCI performed through the femoral artery can also result in a longer hospital stay.

8. If you do not wish to participate or wish to end participation in the study
You decide whether or not to participate in the study. Participation is voluntary.

If you do not wish to participate, the PCI procedure with the thicker catheter will be performed in the usual manner. This can be done through the groin or the wrist.

If you do participate, you can change your mind and withdraw at any time, even during the study. You will then receive the standard treatment again. You do not have to provide a reason for stopping. If the procedure has already begun, it cannot be

reversed and you will also require a follow-up check-up. The data collected up to the moment of withdrawal will be used for the study.

9. End of the study

Your participation in the study ends when:

You have had the check-up one month after the procedure;
You choose to stop;

The researcher feels it is better for you to stop;

The Isala cardiology partnership, the government or the supervising medical.
The entire study is complete when all participants are finished.

10. Use and storage of your records

All of your records will remain confidential. To protect your privacy, your records will be given a code. Your name and other information which directly identifies you will be omitted. The records can only be traced back to you with the key to the code. Only the study doctor and research staff know which code you have. The study will only ever use your data with that code, never with your name. The key to the code will remain in possession of the study team. Reports on the study will also only use that code.

Some people will be allowed to access your medical and personal information. Access to your medical and personal Information will be by the study Doctor/Investigator and the research team at site. The Sponsor, representatives of the Sponsor (including the Contract Research Organisation, study monitors, auditors and project manager. Ethics committee and government agencies where permitted or required by law. This is necessary to confirm that the study has been conducted properly and reliably. - They will keep your information confidential. By signing the consent form, you agree to the collection, storage and viewing of your medical and personal records.

11. More information on your rights with regard to data processing

All the information that is collected during the study is kept confidential and there are strict laws in place which safeguard the privacy of the patient at every stage. We will be using your information (samples and medical records) in order to undertake this study and we will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Your identity and contact details will be confidential and all the data collected will be anonymized so you cannot be

identified.

A description of this study will be available on http://www.ClinicalTrials.gov, and this web site will not include information that can identify you.
ISALA Heart Centre, Zwolle, is the Sponsor for this study based in the Netherlands. We will be using information from your medical records in order to undertake this study and will act as the data controller for this study. This means that we are for looking after your information and using it properly. ISALA Heart Centre will keep identifiable information about you for 15 years after the study has finished. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

The local site will keep your name, ID number and contact details confidential and will not pass this information to ISALA Heart Centre. The local site will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for you care, and to oversee the quality of the study. Certain individuals from ISALA Heart Centre and regulatory organisations may look at your medical and research records to check the accuracy or the research study. ISALA Heart Centre will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

12. Insurance for subjects

If you participate in the study you will face the same risks as for the standard treatment of your condition. The study is insured with HDI Global SE – UK Policy Number 390-08414363 and has a liability insurance for £5 million.

13. Informing your GP

We will always notify your GP and/or treating specialist that you are participating in the study. This is for your own safety. If you do not agree to this, you cannot participate in the study. In the event of complications, we may contact your doctor or GP for information such as your medical history or use of medicines.

15. Questions

If you have any questions or concerns, please contact the study doctor or the research team.

If you have any complaints or require general advice you can contact the hospital's Patient Advice and Liaison Service (PALS).

16. Signing the consent form

Once you have had sufficient time to think about it, you will be asked to decide whether or not to participate in this study. If you consent, we will ask you to confirm your consent in writing on the appropriate consent form. By giving your written consent, you acknowledge that you have understood the information and agree to participation in
the study.

The signature sheet will be kept by the researcher. You will receive a duplicate or a second copy of the consent form.

Thank you for your reading this information sheet.

Consent form

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- I have read the information letter. I was given the opportunity to ask questions. My questions have been answered to my satisfaction. I have had enough time to decide whether or not to participate. I am aware that participation is voluntary.
- I am also aware that I can decide not to participate or to withdraw from the study at any time. I need not give a reason for this.
- I consent to informing my GP that I am participating in this study.
- I am aware that some people have access to my records. Those people are listed in this information letter.
- I consent to the collection and use of my information in the manner and for the purposes listed in the information letter.
- I consent to the storage of my information at the research site for 15 years after this study.
- I wish to participate in this study.

Name of participant:
Signature: Date : __ / __ / __

Name of investigator:
Signature: Date : __ / __ / __
