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## **Participant Information Sheet**

### **Barts Sex-CAD Database: Do female sex hormone levels inform inflammatory status and susceptibility in women suffering coronary artery disease?**

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**Version number and date**

Version 1.4, 02/06/2025

**Researcher's name**

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**IRAS number:** 316012

**Invitation paragraph**

You are being invited to take part in a research study. Before deciding to take part, it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

One of our research team will go through the information with you to make sure that you understand. Ask us if there is anything that is unclear or if you would like more information or more time. Queen Mary University of London (QMUL) is the Sponsor of this research.

**What is the purpose of the study and what would taking part involve?**

There is a lack of understanding of how Coronary Artery Disease (CAD) – meaning the blocking or furring up of the arteries of the heart – starts and progresses in women. In both men and women CAD is the most common cause of heart attacks, which occur when the blood supply in the heart is interrupted (these are also known medically as 'acute coronary syndromes').

Before the menopause women appear to be protected from CAD; however, after the menopause that protection is lost. Also, those women who do suffer a heart attack have twice the risk of further heart attacks compared to men despite having the same treatment that works well in men. Biological differences between men and women are probably playing an important role in the way CAD develops. However, due to a lack of research there is currently little understanding of how the female body works in this area. Hormones such as oestrogen and testosterone are also likely to be contributory factors. We think the differences in hormones play a part in CAD in both men and women are important, but the role they play is not yet fully understood.

In this study would like to conduct questionnaires with patients with CAD, to understand their hormone status and how parts of their medical history may be a contributory factor. We will combine this data with the data regarding your condition that is routinely collected by the hospital. In this way we hope to understand whether hormone status plays an important role in CAD. Our hope is that through this research we will address an under researched area and find new ways of treating women and men with coronary artery disease.

You will be contacted by a member of the research team which may be several months/years following your discharge from Barts Heart Centre. You would be consenting to take part in a telephone questionnaire which will also be conducted by a member of the clinical team. For women this will involve questions about your menstrual (period) history, and other relevant history that might affect your hormone levels. For men this will involve questions about relevant history that might affect your hormone levels. Your responses will be logged by a member of the clinical team into a secure database. A member of the clinical team will also check your electronic patient record at a later time to gather outcome data. Your confidentiality is of top priority therefore any data used will be anonymised before data analysis takes place. We would also like to obtain your consent to be contacted in the future regarding additional research studies relating to the area of understanding differences in CAD between women and men. Your direct participation in this study will only be for required for the short duration, only for participation in the questionnaire over the phone (approximately 10 minutes).

**Why am I being invited?**

You have been chosen because you have previously presented to Barts Heart Centre with chest pain. We are inviting all patients who have presented to Barts Heart Centre with chest pain to participate.

**Do I have to take part?**

NO. It is up to you to decide whether or not to take part. The purpose of this information sheet is to help you make a decision. The study will also be explained to you by a member of the research team. If you decide to take part you will be asked to sign a consent form. You are free to withdraw from the study at any time without giving a reason. A decision to participate, not participate or withdraw from the study will not affect your medical care.

**What are the possible benefits of taking part?**

There will no personal benefit to taking part but the main benefit of this study is that it aims to further the knowledge and understanding for women with CAD. Ultimately, we hope it will allow us to provide better and more targeted treatments to women in the future.

**What are the possible disadvantages and risks of taking part?**

No additional procedures are required to take part therefore there is no significant expected harm from this study. Your confidentiality is of top priority therefore any data used will be anonymised before data analysis takes place.

**Expenses and payments**

N/a

**What information about me will you be collecting?**

As explained above we will be collecting information using questionnaires conducted by a member of the clinical team When anonymised this data will be compared with other routine clinical data to explore links. The other clinical data relevant to this study is already collated on a secure database at Barts Heart Centre.

**When and how will my data be destroyed?**

The study duration is 8 years. Paper records will be stored/accessed for 12 months-3 years after the study has ended. The electronic database will be retained for up to 5 years. For studies involving Barts Health NHS Trust patients and sponsored by Queen Mary, University of London staff, the approved repository for long-term storage of local records is the Trust Corporate Records Centre.

**How will we use information about you?**

We will need to use information from you/from your medical records for this research project. This information will include your initials/ NHS number/ name/ contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

If we note any significant abnormalities on the extra blood test performed, we will write to your GP to inform them, as well as providing a referral to an appropriate specialist clinic if applicable.

Research data will be used by the research team involved in this study for the purposes of analysis. Any information shared electronically between the team will be encrypted. Fully anonymised data will eventually be shared with fellow researchers via conference presentation and via publication in scientific journals. This study also forms part of a PhD project and therefore data will be used in the production of a PhD thesis.

**What are your choices about how your information is used?**

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information:

- at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
- by asking one of the research team
- by sending an email to [a.j.sullivan@qmul.ac.uk](mailto:a.j.sullivan@qmul.ac.uk) or [k.s.rathod@qmul.ac.uk](mailto:k.s.rathod@qmul.ac.uk)
- By sending an email to the QMUL data protection officer [data-protection@qmul.ac.uk](mailto:data-protection@qmul.ac.uk)

**What will happen if I want to withdraw from this study?**

You are free to withdraw from the study at any time. If you decide to withdraw this will not impact on your usual medical treatment.

**What should I do if I have any concerns about this study?**

If you have any concerns about the manner in which the study was conducted, in the first instance, please contact the researcher(s) responsible for the study Dr Andrew J Sullivan [Sub-investigator] and Dr Krishnaraj S Rathod [Chief investigator]. If you have a complaint which you feel you cannot discuss with the researchers, then you should contact the NHS PALS service:

The Royal London & Mile End Hospitals - 0203 594 2040 [RLHpals.bartshealth@nhs.net](mailto:RLHpals.bartshealth@nhs.net)  
Whipps Cross Hospital - 0208 535 6438 [WXpals.bartshealth@nhs.net](mailto:WXpals.bartshealth@nhs.net)

Newham University Hospital - 0207 363 9292 [nuhpals.bartshealth@nhs.net](mailto:nuhpals.bartshealth@nhs.net)  
St Bartholomew's Hospital - 0203 465 5919 [SBHpals.bartshealth@nhs.net](mailto:SBHpals.bartshealth@nhs.net)

**Who can I contact if I have any questions about this study?**

If you require any further information please contact:

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