Participant Information Sheet for Patients With Dilated Cardiomyopathy

UCL Sponsor Reference Number: 143656

Study Title:
The arrhythmogenic potential of midwall septal fibrosis in non-ischaemic dilated cardiomyopathy – a combined CMR and ECGI investigative study

Department:
Institute of Cardiovascular Science, University College London

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1. Introduction

We are inviting you to take part in a research study. Before you decide it is important for you to understand why the 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. Ask us if there is anything that is not clear or if you would like more information.

2. What is the project's purpose?

Dilated cardiomyopathy is a common heart condition in which your heart weakens, enlarges and stops pumping efficiently. Worryingly, some people with this heart condition experience dangerous heart rhythms for which they need a special "defibrillator" put in. But because these defibrillators can have unwanted side effects, they are not implanted into everyone. We need to better understand which patients are at high risk of dangerous heart rhythms so we can be better at choosing who to implant them in.

In this study, we will take MRI pictures of your heart and look at the electrical rhythm with a special vest. From this, we can generate computer models of your heart to predict if you are at higher risk of a dangerous heart rhythm. We think this will improve our understanding of the heart's electrical activity and help us identify patients who need defibrillators.

3. Why have I been invited?

You have been invited because you have been diagnosed with dilated cardiomyopathy.

4. Do I have to take part?

No, your involvement is voluntary and it is up to you to decide if you would like to participate in this study. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. You can opt out of some or all of the assessments at any time. If you decide not to participate, this decision will not in any way affect any medical or NHS treatment you currently receive.

5. What will happen to me if I take part?

Participating in this study will involve a single trip to the University College London (UCL) Bloomsbury Centre for Clinical Phenotyping in central London. The clinic visit will last around two hours. We will find a date and time that suits you.

When you arrive, we will:

1. Start by asking you some questions about your health and log your responses. We will collect background information about you, like your full name, date of birth, your contact details and your ethnic group. We will also ask you about your medical history, family history, and obtain details from your medical records, and previous and future images until the end of the study.
2. Examine you briefly (for example, listen to your heart and lungs with a stethoscope), and measure your blood pressure, height and weight.
3. Print an ECG trace of your heart rhythm.
4. Take measurements of your heart's electrical activity with our special ECG vest before and after a brief bike exercise while resting on a bed.
5. In your arm or hand, we will insert a cannula. This is a tiny tube that sits in your vein.
6. Collect blood samples for testing directly from the cannula so in most cases no further needle puncture will be needed. We will look at your kidney function and your blood count. We will also collect extra blood samples that will be kept securely in the university laboratory's freezer. These will be used for future small molecule or gene code analysis or to derive pluripotent cells.
7. Collect a urine sample that will be securely stored in the university laboratory's freezer, for future protein/small molecule analysis.
8. Perform a cardiac MRI scan of your heart.
9. This marks the end of your tests and clinic visit.

6. What does the creation of pluripotent cells involve?

We may use the cells taken from your frozen blood sample to create a type of cell known as a pluripotent cell. This type of cell can be used to create different types of tissue, including heart muscle cells. Your cells might be used in research involving genetic alteration of the cells and to help us discover new treatments for heart muscle diseases.

7. What does the brief bike exercise involve?

Once you have worn the ECG vest and we have taken a recording with you lying on a couch, we will invite you to perform gentle exercise using a bed bike at a slow pace for a few minutes. This will gently exercise your heart and we will collect ECG information during this exercise period. Please wear comfortable shoes to the appointment in order to be able to pedal on the bed bike.

8. What does the cardiac MRI involve?

MRI stands for Magnetic Resonance Imaging and produces an electronic picture of heart using a magnet instead of an X-ray. This MRI scanner is housed within the same building as the rest of the tests.

People with advanced kidney disease will not be eligible for the heart MRI scan and we will ask you about these conditions when we call you. We will also check your kidney function before the scan on the day of your visit to make sure it is safe to proceed. If your kidney function is found to be too low, you will not be eligible for a heart MRI.

When we call you before your appointment, we will ask you some questions to make sure it is safe for you to have the MRI. If you have a metal implant we will check whether you can still safely have an MRI. For example, certain metal implants like a knee replacement or a coronary stent, are completely safe. If you have certain other types of metal implants however, such as a cardiac pacemaker, aneurysm clip, implanted insulin/drug pump, neurostimulator (TENS unit), or cochlear implant, we will then not perform the MRI. It is essential that you tell the study team if there is any possibility that you might have any type of metal in your body.

On the day of your appointment and just before you enter the scanner room, you will be asked to remove any dentures, hair clips, combs, earrings, and necklaces. You will still be wearing part of the ECG jacket when entering the scanner room, but additional ECG stickers will also be placed on your chest and a blood pressure cuff will be placed on your arm so we can monitor your heart.

When you are ready to go into the scanner you will be asked to lie flat on your back on the scanner bed, which will then slide gently into the scanner. During the heart MRI scan you will receive some instructions to hold your breath, to allow for pictures to be taken but for most of the time you will be able to breathe freely. We will use a contrast called gadolinium to improve the pictures we take.

A radiographer or doctor operates the scanner from behind a window, and will be able to see and hear you throughout the procedure. You will be able to press a button when you are in the scanner to tell the study team how you are getting on. As the scanner makes a loud noise we will provide you with ear protectors to ensure you are comfortable. The scans will take no more than one hour to complete. Before you leave the scanning department, you will be given time to rest and ask any questions you may have about the study. We will give you a telephone number for you to call if you have any problems or concerns and wish to speak to one of the researchers.

9. What is the contrast agent gadolinium and what are the risks?

We often use a contrast agent ('dye') for MRI scans; this enhances and improves the quality of the images. The contrast agent is called "gadolinium" (or gadoterate meglumine); it is very widely used and usually has no side effects at all. Very occasionally (less than 1/100 times), it may cause a temporary mild headache or nausea. We have previously performed research scans using this dye on a vast number of healthy volunteers as well as young and older patients without any complication.

We would be unable to use this dye if:

a) You had severe kidney disease (defined as eGFR <30ml/min) - we will test your kidney function before the MRI scan to determine your kidney function.
b) You have previously had a severe adverse reaction to gadolinium
c) If you are pregnant or breastfeeding

10. What are the possible disadvantages and risks of taking part?

Although uncommon, there is the potential risk of skin irritation from the ECG stickers. If this is known about beforehand, we will attempt to use alternate adhesive agents. Venous cannulation is a routine medical procedure that has minimal risk when performed by trained personnel. A cannula is a flexible tube containing a needle that is inserted into a vein in your hand or arm. The blood sample will be drawn from this cannula. The dye will be injected through the cannula during the scan. Some people feel lightheaded following insertion of a cannula and there is a risk of fainting. To minimise these effects, the cannula will be inserted in the vein while you are sitting or lying down. Having a cannula inserted can cause some discomfort and there is a very small risk of blood clots, bruising and infection.

A bike exercise is generally safe and complications at the low workload you will be doing are extremely rare. Possible complications of an exercise stress test are low blood pressure during or immediately after exercise, possibly causing you to feel dizzy or faint. In that case we would simply stop the bike exercise and the problem should go away. Abnormal heart rhythms (arrhythmias) can sometimes occur during an exercise test but again they usually go away soon after you stop exercising. Although extremely rare, it is possible for an exercise test to cause a heart attack – we consider this to very unlikely because of the low workload and gentle exercise pace that you will be undertaking.

The MRI scans are very safe. The cardiac MRI scanner is noisy but not at all painful. Some people experience feelings of claustrophobia during the scan, but there is constant

contact via an intercom system so the participant can request the investigation be paused at any time. We can also offer to scan you in different positions to make you as comfortable as possible. You can talk to us during the scan and if you wish, a member of our research team, or your accompanying relative/partner, can sit by your side on a chair in the scanner room, for the entire duration of the scan. You can request the scan to be stopped at any time simply by talking to us or pressing a button.

11. What are the possible benefits of taking part?

While there are no immediate benefits for those people taking part in our study, it is hoped that this work will enhance our understanding of the heart. As your MRI scan will have been clinically indicated and requested by your clinical team we will provide your clinical care team with a complete report of the MRI scan. We will let you and your doctor know if we find any unexpected abnormalities on the MRI scan that require medical attention. You should be aware that being in a research study does not take the place of routine physical examinations or other check-ups with your doctor, and should not be relied upon to diagnose or treat medical problems.

12. What if something goes wrong?

If you have any concerns about the clinic visit you can speak to a member of the research team who will do their best to answer any questions. Contact details are at the end of this information sheet.

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, UCL complaints mechanisms are available to you. Please contact the UCL JRO at research-incidents@ucl.ac.uk. Please ask a member of the research team if you would like more information on this.

In the very unlikely event that you are harmed by taking part in this study, compensation may be available to you. If you suspect that the harm is the result of the Sponsor's (UCL) negligence, then you may be able to claim compensation. After discussing with the research team, please make the claim in writing to Dr Gabriella Captur, who is the Chief Investigator for this research study and is based at the Institute of Cardiovascular Science at UCL. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

13. Will my information be kept confidential?

All the information you give us and the results from the tests will be treated in the strictest confidence. They will be stored securely and will be the responsibility of the Institute of Cardiovascular Science at UCL. Only your clinical team at the Royal Free Hospital will have access to your personal identifiable information that will never leave the Royal Free Hospital. These data will be stored in an NHS computer and secure behind the NHS firewall at the Royal Free Hospital site. Only coded (pseudonymised) research data will be stored on in the Data Safe Haven at UCL, and this will only be accessible by the Chief Investigator and essential members of the research team. Therefore, research data will be stored separately from personal data (such as name and address). In some cases, the genetic information produced by studying the detailed DNA code may be placed in an electronic archive with no connection to your name or other personal identifier for the benefit of scientific understanding. This archive will only be accessible to appropriate doctors and researchers who have been approved, in order to ensure the results are only used to advance scientific and medical understanding. Although there is a theoretical possibility that a participant could be identified by the deposited information (e.g. if the same participant in the future entered into another independent genetic study), this is extremely unlikely.

We shall keep the information for 20 years after the end of the study, as usual practice. We will protect your personal information in accordance with UCL sponsored study Information Governance policy; the handling, processing, storage and destruction of data will be conducted in accordance with the General Data Protection Regulation (GDPR) and UK Data Protection Act (2018) to ensure that confidential information is safeguarded.

14. How will we use information about you?

We will need to use information from your medical records for this research project. This information will include your NHS number, name, and 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. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

15. 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.
If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

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

- At www.hra.nhs.uk/information-about-patients/, or www.ucl.ac.uk/legal-services/privacy
- From our leaflet, available from one of the study team
- By asking one of the research team
- By sending an email to f.chan@ucl.ac.uk or Sponsor Data Protection Officer data-protection@ucl.ac.uk
- By ringing us on 020 7679 9409

17. I have consented to being part of this study, but what happens if I lose my ability to consent after this?

If this happened, you will be withdrawn from the study. The data or tissue already collected with consent would be retained and used in the study. No further data would be collected or any other research procedures carried out on or in relation to you.

18. Limits to confidentiality

Please note that assurances on confidentiality will be strictly adhered to, but may be limited and conditional as the researcher has a duty of care to report to the relevant authorities possible harm/danger to the participant or others.

19. What will happen to the results of the research project?

We will publish the results of our research in medical and research journal. References to all the publications will continue to be available on our project-specific web site. No one in the study will be identifiable in any report or publication.

20. Expenses and payments

You will not receive any payment for participating in this study. If you are a patient with dilated cardiomyopathy and your scan is clinically indicated and requested by your clinical care team, we would not be able to reimburse travel costs to and from UCL, however feel

free to speak to us if this is crucial for your attendance and we will check what can be offered.

21. Local Data Protection Privacy Notice

The controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk

This 'local' privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our 'general' privacy notice:

University College London (UCL) aims to conduct research to the highest standards of research integrity. Our research is underpinned by policies and procedures that ensure we comply with regulations and legislation that govern the conduct of research; this includes data protection legislation such as the General Data Protection Regulation (GDPR) and the Data Protection Act 2018 (DPA).

UCL uses personal data to conduct research to improve health, care and services. As a publicly-funded organisation incorporated under a Royal Charter, we ensure that it is in the public interest when we use personal data from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your personal data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. Most of our health and care research follows the UK Policy Framework for Health and Social Care Research.

The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices.

Your personal data will be processed so long as it is required for the research project. If we are able to anonymise or pseudonymise the personal data you provide we will undertake this, and will endeavour to minimise the processing of personal data wherever possible.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk.

22. Who is organising and funding the research?

The research study is funded by the British Heart Foundation. The research is organised by the study team at the Institute of Cardiovascular Science at UCL

23. Contact details

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Thank you for reading this information sheet and for participating in this research study.

Please find overleaf:

- Consent Form
- MRI Safety Questionnaire