Imperial College London

PARTICIPANT INFORMATION SHEET
(obesity cohort)

1. Study title

This is a research project to study the electrical properties of the heart to understand why some people have heart rhythm problems.

The formal scientific title of the study is, "Electrophysiological Phenotyping Of patients at Risk of Ventricular Arrhythmia (EPORVA study)".

2. Invitation paragraph

You are being invited to take part in a research study.

Before you decide if you want to take part in this study, it is important for you to understand why the research is being done and what it will involve.

Please take the time to read all of the information carefully. Ask a member of the research team if there is anything that is not clear or if you would like more information.

Take as much time as you need to decide whether or not you wish to take part.

If you agree to take part, you will be asked to fill out, sign and date a consent form and keep a copy with this information sheet, as a useful reference on the study and contact details.

Thank you for reading this information.

3. What is the purpose of the study?

Obesity can affect the heart's electrical circuit. This can increase the risk of heart rhythm problems.

The first aim of this study is to better understand the electrical activity of the heart in patients who have obesity.

Obesity can be treated with specialist surgical treatment.

The second aim of this study is to understand if surgery for obesity also has added benefits on the heart, to reduce the risk of heart rhythm problems.

To achieve these aims, we will use a new method that combines recordings of the heart's electrical activity with heart scans to study the heart's electrical properties.

The scientific name for this new method is "electrocardiographic imaging". You may find it easier to remember and call it **"ECG-I"**.

This new method (ECG-I) will give more detailed information about the heart's electrical properties compared to other available or routine tests.

Specifically, we will conduct ECG-I **before** and **after** weight-reduction surgery. This will allow us to compare the heart's electrical properties before and after surgery.

With this information, we hope to understand **how** heart rhythm problems develop in obesity and **what** can be done to prevent it.

A more detailed, step-by-step explanation of this study and the ECG-I method is included in section 9 (page 3) of this document.

Importantly, this study is **NOT** intended to influence, determine or change any of your ongoing or planned treatment.

4. Why have I been invited?

You have been invited to take part in this study because you are awaiting weight-reduction surgery.

Taking part in this study does **NOT** mean you have a new diagnosis of heart disease, heart rhythm problem or any other medical problem.

5. What are the conditions of my taking part?

Similar to all scientific studies, our study has certain criteria that participants need to fulfil to take part.

To participate in the study, you need to:

- Be awaiting weight-reduction surgery
- Be aged eighteen (18) to seventy-five (75) years
- Be able to provide verbal and signed written informed consent

You cannot participate if you are pregnant, breastfeeding, outside the specified age range, cannot provide consent, or cannot undergo the study tests detailed in this document.

Please let us know if you think you might be pregnant, or are breastfeeding.

All women of a child-bearing age will be offered a pregnancy test on the day of recruitment to the study, and again before they undergo ECG-I.

6. Do I have to take part?

It is completely up to you if you want to take part in the study or not.

If you decide to take part you are still free to stop participating in the study and withdraw at any time. In this case, your doctor may ask you why you want to withdraw but you do not have to give a reason. If you decide to withdraw during the study, the care that you receive will not be affected in any way.

If you agree to participate in this study, your GP will be informed that you have agreed to take part.

7. What are the possible benefits of taking part?

It is likely that there will be no direct benefit to you by taking part in this study.

However, if you wish to take part in the study, you will be helping us to learn more about heart rhythm problems and to improve its treatment.

Your treatment or care will **NOT** be affected by your decision to take part or opt out of taking part in the study.

8. What do I have to do?

You must be willing to be contacted by the research team, have the assessments that form part of the study and attend the study follow-up visits.

You will continue to receive care from your GP or your hospital doctors as usual.

It is important that you inform the research team of any medications that you are taking before taking part in the study and any new medications that you may start taking during the study.

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

Please read this section carefully for a step-by-step explanation of the study.

1) **You will be given study information**
You will be given full written and verbal information about the study at your meeting with the doctor, nurse or other qualified specialist.

If you agree to take part in the study you will be given a study identification (ID) code and you will be asked to provide signed, written informed consent to take part in all of the study tests.

2) **You will have an initial medical assessment**
You will then have the following assessments which will be performed by an experienced and qualified member of the clinical or research team.

a. **Medical history and physical examination (including height, weight, blood pressure, heart rate)**
This is to make sure that it is safe for you to take part in the study.

b. **Routine blood tests (if not already done).**
Blood tests will only be taken if we cannot access any blood results from the preceding 3 months before you enrol to the study. The research team will not be able to identify you from your blood test results. The blood test results will be used to investigate how they relate to the electrical activity of the heart. Blood samples will be processed, analysed and stored according to Imperial College Healthcare NHS Trust policy.

c. **12-lead electrocardiogram (ECG)**
This is a routine, painless 10 second recording of your heart's electrical activity at rest. We will use this to study the heart's electrical activity.

d. **Pregnancy test for female participants of child-bearing age**
All female participants of child-bearing age will undergo a urine pregnancy test at enrolment. This is to make sure it is safe for you to participate in the study.

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3) **You will be given a date and time for ECG-I**
You will be asked to provide contact details and identify how you would like to contacted. This is so that we can arrange for you to attend the Hammersmith Hospital for ECG-I.

You will be contacted by a member of the research team in the following weeks to arrange a date and time that is convenient for you.

In some cases, we may be able to assist with transport to and from Hammersmith hospital.

4) **You will have ECG-I:**
ECG-I is made up to two separate tests: first, a recording the heart's electrical activity at rest and with physical activity; second, a MRI (or CT) scan.

Female patients of child-bearing age will be offered a urine pregnancy test again.

a. **Recording the heart's electrical activity**
This is a painless test that gives more detailed information than a standard ECG.

It involves applying strips of sticky pads to your chest and back.

We will record the electrical activity of your heart at rest and during a form of physical activity. The physical activity will depend on what you are comfortable doing. For example, it might involve cycling on a bicycle or rotating a handle bar. We will talk to you to decide the test that you feel comfortable doing.

The aim of the test is to increase your heart rate **without** making you feel unwell. This will take approximately 10 minutes.

b. **Chest MRI or CT scan**
You will have new strips attached to your chest and back, followed by a chest scan. This will take approximately 15-30 minutes and will give us information about the structure of your heart.

5) **You will have your surgery as planned**
You will have your planned surgery which will be delivered by your routine clinical teams. The research team will have no involvement in this aspect of your care.

6) **You will have ECG-I again**
You will be contacted using your preferred means of contact for repeat ECG-I, as detailed above, approximately 3-6 months after your treatment.

The duration of your participation in this study will continue until the last follow-up is complete. You may, however, choose to withdraw from the study at any point.

10. What are the risks and side effects of taking part?

We believe the risks or chances of experiencing any side effects in our study are small.

We have been very careful to consider any potential risks or side effects, and list these below.

We have also had expert guidance in this process.

Blood tests
Not everyone will need blood tests. Sometimes this can cause bruising near the site blood is taken from. This is usually short-lived and is not cause any long-term problems.

Allergies
The risk of an allergic reaction in this study is very small.

However, some people may have known allergies to the stickers used for electrical recordings of the heart.

If you are known to have such allergies please inform the research team during your medical assessment or prior to having the electrical recordings.

ECG-I
You will be asked to undertake a form of physical activity during the electrical recording of your heart. This will be supervised by experienced and qualified staff.

This is intended to increase your heart rate, to simulate exercise, in a safe and highly monitored environment. It is **NOT** intended to make you feel unwell.

You are free to stop the test at any point should you wish without having to provide a reason, or if you feel unwell in any way.

You will also have chest scans as part of this study.

We believe most participants in this study will be able to have a chest MRI scan safely.

Only participants who cannot safely have a MRI scan, do not wish to have or cannot tolerate a MRI scan, will be offered a CT scan.

We estimate less than 5% of participants recruited to the study may require a CT scan.

Chest MRI scans involve no radiation and therefore there is no risk of radiation-related risks or side effects.

If you have any metal devices, including but not limited to, pacemakers, defibrillators, implants, prosthesis, shunts, plates, pins, joint replacements, shrapnel injuries, dental fillings, or recording devices please inform a member of the team before your MRI scan. You will be asked a series of questions before the MRI scan to ensure it is safe for you.

The experience of MRI during pregnancy is limited. Although there are no known harmful effects of MRI to the unborn fetus, there is may be a possibility that harmful effects could exist. Therefore, you will be offered a pregnancy test before the physical test and MRI scan. A positive urinary pregnancy test means that you will not be able to participate, or continue your participation, in the study.

A CT scan is a powerful xray machine, and involves radiation. If you cannot safely have a MRI scan and need a CT scan instead, you will be required to lie flat on a bed, and pass into a ring for the CT scan. It is quicker than a MRI scan and will take about 10 minutes. It is less noisy than a MRI scan.

If you cannot safely have an MRI scan, you will have a maximum of two CT chest scans.

These will be extra to those that you would have if you did not take part in the trial. These procedures use ionising radiation to form images of your body and provide your doctor with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous.

We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to about 50% of people at some point in their life. Taking part in this study will increase the chances of this happening to you from 50% to 51%.

All tests will be conducted by trained healthcare professionals, experienced members of the research team and/or medically trained staff in a safe clinical environment.

11. What happens when the research stops?

Throughout and after the study has finished, you will continue to receive care from your GP and other healthcare professionals responsible for your care.

If you withdraw from the study before the end of the tests, or lose your ability to give informed consent during the study, you will be withdrawn from the study.

If you lose your ability to consent for a procedure or withdraw from the study for whatever reason, the data that has already been collected will be used for analysis.

No personal information will be used in analysis.

12. What if new information becomes available?

Sometimes during the course of a research project, new information becomes available which affects the study. If this occurs, we will inform you and discuss with you whether you wish to continue with the study. If you decide to withdraw from the study, your anonymised data that has already been collected will be used for analysis but no more data will be collected from that point in time. If you decide to continue with the study, you will be asked to sign an updated consent form. Also, on receiving new information, your research team may consider it to be in your best interest to withdraw you from the study. Your research team will explain the reasons if this occurs.

If during the course of the study, for whatever circumstances, you are no longer able to provide consent to continue taking part in the study, your ongoing participation in the study will cease immediately from that point in time. Any identifiable data or tissue already collected with your consent would be retained and used in the study. However, no further data would be collected or any other research procedures carried out on you thereafter.

Your participation in this study will not influence, affect, prejudice or in any way change your ongoing, planned or future treatment or care.

13. What if something goes wrong?

It is unlikely that you will come to significant harm if you choose to take part in this study.

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Dr Fu Siong Ng, Tel: 0207 594 3614). The normal National Health Service mechanisms are also available to you.

If you are still not satisfied with the response, you may contact the Imperial College, Joint Research Compliance Office or PALS (Ground floor, South Corridor B, Hammersmith Hospital, Du Cane Road London W12 0HS; Tel: 020 3313 3322; email: imperial.pals@nhs.net).

14. What will happen to the results of the research study?

The results of the research will be offered for publication in recognised medical journals but you will not be identified in any report or publication. We will be able to let you know about the results at the end of the study.

15. Who is organising and funding the research?

The study is being organised by members of research team who are paid by the National Health Service and Imperial College London.

The study will be funded by National Institute of Health Research Biomedical Research Imperial College Biomedical Research Council (NIHR BRC).

16. Who has reviewed this study?
The XXX Research Ethics Committee have reviewed and approved the study.

17. Data protection and patient confidentiality: GDPR transparency and legal statements

Imperial College London is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep identifiable information about you for 10 years after the study has finished in relation to consent forms, participant identification codes/logs and primary research data.

However, all other identifiable data such as contact details that will be kept securely during the study will be irretrievably deleted or disposed at the end of the study.

Further information on Imperial College London's retention periods may be found at https://www.imperial.ac.uk/media/imperial-college/administration-and-support-services/records-and-archives/public/RetentionSchedule.pdf .

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.

All participants will have an anonymous identifier that will be generated by the research team during the recruitment process. Participants will be entered into a study database which will contain all research records. This database can be accessed at the National Heart and Lung Institute (NHLI) at the Hammersmith Hospital and specific PCs that are used by the research team within the Robert Steiner MRI Unit, Imperial College, MRC Clinical Sciences Centre, Hammersmith Hospital.

If you need to have blood tests, this will be done by trained, qualified and experienced members of the research team. Your blood tests will be labelled with your usual NHS identification information and processed under the remit of Imperial College Healthcare NHS Trust. The results of these will be available to the clinical teams responsible for providing your care. Importantly, the research team will not store, process, retain or use the blood samples themselves at any point during the study. Imperial College Healthcare NHS Trust policies will apply to the handling, processing, storage, retention and analysis your blood samples. Only authorised members of the research team will have access to the results of your blood tests via Imperial College Healthcare NHS Trust. These results will then be entered and stored in an anonymised format on the password protected, and restricted-access study database.

If you are female and of childbearing age, you will be asked to provide urine samples to test for pregnancy. These samples will be tested immediately when they are provided. They will not be labelled with identifiable information, and will be discarded immediately after a pregnancy test has been performed using the urine sample. No urine samples will be stored, retained, processed or used for any other purpose by the research team.

MRI scans will be performed at the MRI Robert Steiner MRI unit based in Hammersmith Hospital. A written ledger of identifiable information on individuals scanned is kept at this unit. However, only authorised members of the research team will have access to this information, including those based at MRI unit trained to perform the scans. Anonymised imaging records

and data are also held on a password protected database with firewall at the MRC Robert Steiner MRI unit, and only authorised members of the research team will also have access to this.

CT scans, where required, will be performed at the Hammersmith Hospital. This will be performed by Imperial College Healthcare Trust and the scans will be available on the Trust software and computer systems. Imperial College Healthcare NHS Trust policies will apply to CT scanning, processing and handling of imaging data in this instance. Only authorised members of the research team who have a honorary contract with Imperial College Healthcare Trust will have access to the CT scans and the results for the purposes of research as outlined above.

All imaging data, MRI or CT, will be entered and stored in an anonymised format on a password-protected, and restricted-access study database.

You can find out more about how we use your information by contacting the Principle Investigator, Dr Fu Siong Ng, using the contact details provided at the end of this document.

LEGAL BASIS

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information 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 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. We do this by following the UK Policy Framework for Health and Social Care Research.

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (EC) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

CONTACT US

If you wish to raise a complaint on how we have handled your personal data or if you want to find out more about how we use your information, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

Imperial College London

Imperial College Healthcare NHS Trust and Imperial College London will collect information from you and your medical records for this research study in accordance with our instructions.

Imperial College Healthcare NHS Trust and Imperial College London will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Imperial College London and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Imperial College Healthcare NHS Trust will pass these details to Imperial College London along with the information collected from you and your medical records. The only people in Imperial College London who will have access to information that identifies you will be people who need to contact you to for the research study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

Imperial College Healthcare NHS Trust and Imperial College London will keep identifiable information about you from this study for 10 years after the study has finished.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government. Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Contact for further information

Should you have any further questions about the study, or in case of an emergency please contact:

Dr Kiran Patel, Clinical Research Fellow
National Heart and Lung Institute, Imperial College London
4th floor ICTEM building
Hammersmith Hospital
Du Cane Road
London W12 0HS

Dr Fu Siong Ng, Clinical Lecturer and Consultant Cardiologist
National Heart and Lung Institute, Imperial College London
4th floor ICTEM building
Hammersmith Hospital
Du Cane Road
London W12 0HS

Tel: 0207 594 3614

In an emergency, please contact the Hammersmith Hospital Switchboard on: 0203 313 1000 asking to speak with the cardiology registrar on call on bleep 9064

If you have an emergency that is life threatening, please dial 999.

Thank you for reading this information leaflet. Please feel free to contact us if you require further information or clarification.

Please keep this copy of the information sheet and a signed consent form.