Great Western Hospitals
NHS Foundation Trust

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PARTICIPANT INFORMATION SHEET

Observational study recording high fidelity His bundle electrograms to develop pacing algorithms

You are being invited to take part in a research study because you are due to have a pacemaker implanted and we are conducting research in this area. Thank you for reading this information sheet. During this study we are not changing how patients are treated, we simply wish to keep and analyse the information we obtain for research purposes – i.e. keep the observations we make. This type of study is called observational.

Before you decide if you would like to participate, 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 and discuss it with friends, relatives and if you wish, your general practitioner.

Ask us if there is anything that is not clear or if you would like more information.

The Great Western NHS Hospital Trust is the sponsor for this study which is based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and The Great Western NHS Hospital Trust will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The Great Western Hospitals NHS Trust will keep identifiable information about you for 5 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.

You can find out more about how we use your information www.gwh.nhs.uk by contacting Patient Advice and Liaison on 01793 604031.

Key points:

- Your potential involvement in this study is voluntary
- The clinical care that you receive at The Great Western Hospital will not be affected by your involvement, or non-involvement, in this study
- This is a simple observational study so taking part will not change your care or procedure.

What is the purpose of the study?

We would like to store and analyse the electrical signals from your heart recorded during your pacemaker implant.

We would like to examine the signals from the heart during His bundle pacing to further understand them. This may allow, in the future, specific programming of pacemakers to improve their automatic functions and allow early detection of problems.

1. Why have I been invited?

You have been invited because you are awaiting a pacemaker implant.

2. Do I have to take part?

No, you do not have to take part. It is up to you to decide whether or not to take part. If you decide to take part, you are free to withdraw consent at any time without giving a reason. This would not affect the standard of care you receive. If you decide that you no longer wish to continue with the study, we would still retain any data already obtained from you unless you request otherwise.

3. What would happen to me if I take part?

This is an observational study examining the electrical signals obtained during pacemaker implantation and during follow up. The implant procedure is unchanged from a normal pacemaker implant. We would like your permission to store and analyse the data obtained from the electrical signals we record – these are called electrograms (EGMs). Testing occurs routinely pacemaker implantation and during follow up

4. How the observations will be undertaken:

The usual standard pacemaker tests will be undertaken during implant and follow up. For the purpose of the study we would like to collect the signals for analysis obtained during insertion of the pacemaker and follow up. We would also like to use for research the x-ray images acquired during the implant to help understand the position of the pacemaker leads which have been implanted.

5. What will I have to do?

You will need to consent to taking part in this study by signing a form.

6. What is being tested?

This is a purely observational study i.e. this is not a trial of a new treatment we just wish to analyse the data we obtain. This means we will insert the pacemaker in the normal way, and follow you up in the normal way. We wish to use the information we collect as part of your standard care for research.

7. Are there any side effects of participating?

No side effects are anticipated.

8. Are there any other possible risks from taking part? None

9. Are there any costs associated with my being involved in the study

No additional costs are anticipated other than those associated with attending standard clinic appointments which are standard for patients with pacemakers.

10. What are the possible benefits?

There is no benefit for you as an individual taking part in this study. We hope to record and analyse the signals in conjunction with scientists to improve pacemaker safety and automated follow up.

For this research, we are working with scientists based at Aston University in Birmingham (UK) who will help analyse the signals. We are also working with scientists employed by Medtronic, the manufacturers of this particular type of pacemaker. Medtronic manufactures pacemakers, and has research scientists based in Europe and USA who work with clinicians on pacemaker research.

11. What happens when the research study stops?

You would continue to receive routine clinical care. It is anticipated that anonymised results from this study may be published in medical journals, and may be incorporated in pacemaker programming in the future

12. Will my taking part in the study be kept confidential?

Yes. All information about you will be handled in confidence. Data will be stored on The Great Western Hospitals NHS Trust's secure computer servers. Access to the servers is secured with passwords, and the servers are kept in a locked room. All access to the information is logged and can be audited. Anonymised information, where we have removed patient's names and dates of birth, will be shared with scientists working for Medtronic and Aston University in Birmingham, UK.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

1. What if relevant new information becomes available?

Sometimes we (the study investigators) get new information about the procedures being studied. If this happens, one of us will tell you and discuss whether you should continue in the study.

2. Unexpected findings when analysing the collected electrical data

In this unlikely event, we will discuss this with you and inform your general practitioner if appropriate.

3. What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time. We will then just make use of the information we already have about you. We would not then collect any further information.

4. What if something goes wrong or I have a complaint?

Any problems connected to the study would be dealt with initially by the researchers conducting the study (Dr Paul Foley, contact details below). If you wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the Patient Advice and Liaison Service, telephone number 01793 604031

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against The Great Western NHS Hospitals Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). Compensation for any injury caused by taking part in this study will be in accordance with NHS indemnity

NHS bodies are legally liable for the negligent acts and omissions of their employees. If you are harmed whilst taking part in a clinical trial as a result of negligence on the part of a member of the study team this liability cover would apply.

Non-negligent harm is not covered by the NHS indemnity scheme. The Great Western Hospitals NHS Trust, therefore, cannot agree in advance to pay compensation in these circumstances. In exceptional circumstances an ex-gratia payment may be offered.

If you wish to make a formal complaint please contact Patient Advice and Liaison on telephone number 01793 604031

5. Will my taking part in the study be kept confidential?

The Great Western Hospital NHS Trust will use your name, NHS number 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 The Great Western Hospitals NHS Trust and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The people involved are treating clinicians (doctors, cardiac physiologists) assisted, as required, by research nursing staff (if required) will pass these details to The Great Western NHS Hospital Trust along with the information collected from you and your medical records (including x-ray records).

The only people in The Great Western Hospital NHS Trust who will have access to information that identifies you will be people (treating medical staff and cardiac physiologists, assisted, if required, by research nurses) who need to contact you to about your medical care 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, NHS number or contact details.

The Great Western NHS Hospital Trust will keep identifiable information about you from this study for 5 years. If you take part in the study, this will be indicated on your hospital medical records. Some parts of your medical records and the data collected from the study may be looked at by authorised persons from the regulatory authority, or authorised persons from the Great Western Hospitals NHS Trust, to check that the study is being carried out correctly.

All investigators have a duty of confidentiality to you as a research participant and nothing that could reveal your identity would be disclosed outside the research site. The data collected from the study will be recorded anonymously and you would not be identifiable from this. Only anonymised data (i.e. without means of identifying particular patients) will be transferred outside the NHS and will be shared with research scientists working for Aston University in Birmingham, and Medtronic. We may also publish information obtained from participants in this research and will ensure that all identifying information is removed.

6. Involvement of the general practitioner

Your general practitioner (GP) will not be informed of your participation in the study unless you request it as it is a simple observational study. No extra visits to your GP will be required.

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

We anticipate that the results may be published in a scientific journal for the benefit of the wider medical community. However, individual patients will not be identified in any publication and your personal and clinical details will remain strictly confidential. Any scientific publications arising from the study will be available on request to all participants. You would have no legal right to a share of any profits that may arise from the research.

8. Who is organising and funding the research?

The investigators are Dr. Paul Foley, Dr Badri Chandrasekaran, Dr Antony French, Dr Ali Khavandi, Dr Doug Haynes, Mr Matthew Swift and Dr Berthold Stegemann. If you wish to know more about any aspect of the study, or need to get in touch with any of the study investigators, please contact Dr Paul Foley 01793 646214.

Some equipment to record the signals is provided by Medtronic, who will also be involved in analysis of the signals from the heart alongside scientists from Aston University. The Great Western Hospital is sponsoring (organising and running) the study.

9. Who has reviewed the study?

West Midlands Edgbaston Research Ethics Committee on 11 March 2019.

10. Where can I find independent information about taking part in research?

You can contact local branches of the NHS Patient Advisory Liaison Service (PALS). Here is their website: **http://www.pals.nhs.uk/** Tel 01793 604031

11. What do I do next?

The study will be discussed again, when you come in to hospital, and you will be able to ask any questions you may have at that time.

Further information and contact details

Dr. Paul Foley MD FRCP
Consultant Cardiologist
Cardiac Rhythm Management
The Great Western Hospital
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