Portsmouth Hospitals NHS
NHS Trust

Patient Information Sheet for the Study of Implantable Loop Recorders in Haemodialysis Patients

Full Title: Cardio Renal Arrhythmia Study in Haemodialysis patients using Implantable Loop Recorders (CRASH-ILR)

INVITATION

You are being invited to take part in a study. If you decide to take part, 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 one of the research team, who will go through the details with you. Ask if there is anything that is not clear or if you would like more information.

- Part 1 tells you the purpose of this study and what will happen to you if you take part.
- Part 2 gives you more detailed information about the conduct of the study.

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

Thank you for reading this.

Part 1

WHAT IS THE PURPOSE OF THE STUDY?

We are interested in studying the frequency of different heart rhythms in patients who are on haemodialysis. Patients with chronic kidney disease on dialysis may be more prone to abnormal heart rhythms. Dialysis is designed to remove any excess fluid and correct any chemical imbalances in the blood. This function is normally performed by the kidney. Dialysis can remove several litres in a session and change the concentration of certain chemicals in the blood by as much as 50%. These changes may cause abnormal heart rhythms but to date has not been well researched.

It is well known that some patients on dialysis may have episodes where they are more aware of their heart beat (palpitations) or may feel dizzy or even blackout. These symptoms may be caused by abnormal heart rhythms. The frequency of heart rhythm abnormalities in dialysis patients is not fully known.

A number of devices exist that can be implanted under the skin on the chest wall to precisely monitor the heart's rhythm. In this study, we intend to use an implantable loop recorder device, called a Reveal XT to study heart rhythm abnormalities in patients on dialysis. These small devices are implanted in a simple procedure under local anaesthetic in the upper chest, near to the breastbone. They constantly monitor the heart rhythm and record any abnormal episodes. If patients experience any symptoms they have the opportunity to store the heart rhythm information by using a hand held activator, whilst experiencing an episode of palpitations or dizziness. The Reveal XT also stores rhythms automatically to help ensure information is captured when patients are unable to use the activator or do not feel any symptoms.

This recorded heart rhythm data can then be transmitted via a land-line or mobile telephone to a computer for your doctor to analyse the information. A mobile phone unit provided by the Reveal XT manufacturer will be available on the dialysis unit to securely send the information

every time you dialyse. The battery life of the Reveal XT is approximately 3 years. Removing the device is a simple procedure, similar to the process of putting the device in.

WHY HAVE I BEEN CHOSEN?

You have been invited to take part in this study because you are on regular dialysis. You may also have diabetes or thickened or weakened heart muscle seen on an ultrasound scan. Your doctor will have identified you as being suitable for the study based upon your medical history and notes.

We intend to recruit up to 30 patients to the study and follow them up for the duration of the longevity of the Reveal device i.e. approximately 3 years.

DO I HAVE TO TAKE PART? WHAT ARE THE ALTERNATIVES FOR TREATMENT?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

If you choose not to participate there will be no loss of benefits to which you would otherwise be entitled. Taking part in this study is completely your decision. You may decide to stop at any time. You should let your doctor know if you decide to stop.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

We will schedule a convenient time for you to have the following, usually all on the same day:

- An echo or echocardiogram, which is an ultrasound that produces a moving picture of the beating heart on a day prior to dialysis.
- We will also take an electrocardiogram (ECG), a tracing to measure the electrical activity of the heart.
- Then, we will then arrange for you to have the Reveal XT implanted, which must be done on a day, when you are not having dialysis. Prior to the implant procedure, you will be asked not to eat or drink anything for a few hours before hand but you should take all your medicines as usual, unless told otherwise.
- You will be asked to sign a consent form for the implant procedure.
- You will be asked to lie on your back on a couch or bed. Any hair over the upper chest, where the Reveal XT will be placed may be shaved and this area will be wiped with a skin cleanser. The Reveal XT device is slightly smaller than a pack of chewing gum.
- Your chest will be covered with a large sterile drape.
- Your doctor will numb the chest area where the Reveal XT will be inserted with local anaesthetic via a needle. This may sting for a short time until the anaesthetic starts working. The procedure is not painful but let your doctor know if you have any pain or discomfort.
- A small cut approximately 1 inch is made in your upper chest and a ‘pocket’ is made under the skin, where the Reveal XT will be placed. The pocket and skin will be closed using sutures or stitches that dissolve and do not need to be removed. Your doctor may programme the device before a sterile dressing is applied. You will be told when you can remove this dressing. The wound should be kept clean and dry

- until it is fully healed, although it is safe to bathe and shower. Your doctor will arrange to review your wound during a dialysis session in the following week or so.
- After a short while, you will be able to sit up, have a drink and leave for home.
- Before you go, you will be given instruction on how to operate the Reveal XT. Specifically, you will be given and shown instructions on how to transmit the data on the dialysis unit using the mobile phone link provided.
- The procedure involves a small risk of bleeding, bruising and infection to the device site, which will be discussed with you before you agree to sign the consent form.

You will transmit data from your Reveal XT device via the mobile link on the dialysis unit every time you dialyse. If you activate the Reveal XT because of symptoms experienced outside of the dialysis unit - please let us know that you triggered the activator by informing Dr Paul Kalra's research team using telephone number 023 9228 3295 during the weekdays Monday to Friday 9am to 4pm.

The Reveal device does not in anyway replace normal procedures if you were to become unwell and in this case you should ask advice from your GP or emergency services.

As there are some additional visits to the hospital for this study, we can offer to pay for reasonable travel expenses and any car parking charges.

WHAT DO I HAVE TO DO?

You will be offered a mutually convenient date to have your investigations and Reveal XT device implanted under local anaesthetic. You will be required to download data stored by the device either on a monthly basis from home or every time you dialyse on the unit. Extra transmissions can always be sent from home, if you have activated the Reveal XT to store information related to a particular episode. At the end of approximately 3 years, the battery in the Reveal XT will run down and we will organise for it to be removed.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

Implanting the Reveal XT device under the skin carries a very small risk that it might become infected at the time of implantation. This is very unusual but if it does occur would normally be removed. It is not uncommon to have a small amount of bruising after the device has been implanted. This may cause some discomfort but usually settles down very quickly. You are free to take your normal pain relief tablets if you wish.

If you feel worried following your implant, then please contact Dr Paul Kalra's research team using telephone number 023 9228 3295 during the weekdays Monday to Friday 9am to 4pm. Out of hours, please phone the hospital switchboard telephone number 023 9228 6000 and request to speak to the Cardiology Registrar on call.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

There are no benefits from participating in this study but the results may help us develop a better understanding of heart rhythm abnormalities in patients on dialysis. This may help us better treat symptoms or potentially reduce the risk of abnormal heart rhythms in the future.

CONTACT FOR FURTHER INFORMATION

Please discuss with your doctor any questions or concerns you may have regarding your rights as a research subject, research-related injury, and general questions or concerns pertaining to your participation in this clinical study.
If you have any question, please contact:

Dr Paul Kalra, Consultant Cardiologist,
Portsmouth Cardiology, Queen Alexandra Hospital, Cosham, P06 3LY
Tel number: 023 9228 3650

This completes Part 1 of the Information Sheet.

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

Part 2

WHAT IF SOMETHING GOES WRONG?

If you have a concern about any aspect of this study, you should ask to speak with the researcher or your doctor, as detailed above. If you remain unhappy and wish to complain formally, you can do this through the usual NHS complaints mechanism, details of which can be obtained from the hospital.

In the unlikely event that something goes wrong and you are harmed during the research study, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence, you may have grounds for a legal action for compensation against Portsmouth Hospitals NHS Trust, but you may have to pay your legal costs. Agreeing to participate in this study and signing the consent form does not take away any of your legal rights.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

All information, which is collected, about you during the course of the research will be kept strictly confidential. Any information about you that leaves the hospital will have your name and address removed, so that you cannot be recognised from it.

Individuals from regulatory authorities may also inspect the quality of data collected in this study, requiring access to the relevant sections of your medical notes.

INVOLVEMENT OF YOUR GENERAL PRACTITIONER (GP)

We will inform your GP about your participation in this study.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

After the study is completed, all results will be examined and a report may be published in a medical journal. You will not be identified in any report or publication.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

This research is being organised by the Consultant Cardiologist, Dr Paul Kalra at your hospital. He is not paid for including you in the study. The Reveal XT device and mobile phone link unit are being provided by the manufacturer, Medtronic Ltd for the purpose of this research study.

WHO HAS REVIEWED THE STUDY?

This study was given approval to go ahead at this hospital by Southampton & South West Hampshire Research Ethics Committee (A) and Portsmouth Hospitals NHS Trust Research & Development department.

Thank you for taking the time to read this information sheet. You will be given a copy of it (5 pages) and a copy of the consent form (1 page) to keep. It is suggested that you retain these documents for your reference and personal record.