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#### Patient Information Sheet

#### PET CT analysis of peripheral arterial disease before and after angioplasty and its role in restenosis.

You have been asked to take part in a clinical research study. Before you decide whether or not to take part, it is important for you to know why the research is being done and what it involves. Please take time to read carefully the following information about the study before you make your decision and ask us if there is anything that is unclear or if you would like more information. Please feel free to discuss it if you wish with friends, relatives or your personal doctor (i.e. general practitioner). Take time to decide whether or not you wish to take part.

If you are satisfied with this information and wish to take part in this study, you will be asked to sign the consent form; the supervising doctor will also sign it. You are still free to change your mind about taking part even after you have signed the consent form.

The information sheet is in two parts:

* Part 1 tells you why the study is being carried out and what will happen if you take part.
* Part 2 gives you more details about how the study is carried out.

**PART 1**

**What is the purpose of this study?**

Furring up of the blood vessels (arteries) which carry blood to the legs is an important condition. This ‘furring up’ process is known as atherosclerosis and leads to fatty deposits or plaque to build up in the wall of the artery. The process causes the blood vessels to narrow which thus reduces the blood flow to the legs. This can cause either pains in the muscle of the legs on walking or if more severe then can cause ulcers or gangrene in the feet.

The development of atherosclerosis is a gradual process (occurring over many years) and yet we still do not understand how the disease progresses. One of the ways of improving the blood flow to the legs it to use a balloon to stretch open the narrowing’s, a process known as angioplasty. However, even if this procedure is successful, there is a chance that the artery that has been opened with the balloon can narrow again with the symptoms recurring. This process is known as restenosis.

In this study we are looking at whether processes within the artery itself can cause the narrowing of the artery and also predispose to the artery restenosing after angioplasty. Current methods used for looking at blood vessels, such as ultrasound (a scanner used with jelly on the skin to get a picture of the blood vessel and the blood flow through it), can measure how narrow the blood vessel is but they cannot show more intricate chemical processes that occur within the wall of the artery itself.

In order to identify these processes happening in the arteries of the legs, we will use a technique that has been used successfully in patients with disease in the arteries of the heart and brain. This technique involves two types of scanning combined using the same machine (known as a PET-CT scanner). A computed tomography (CT) scan takes lots of pictures of your body and puts them together to show the structures inside your body. A Positron Emission Tomography (PET) scan is a specialised type of scanning that uses radioactive substances or ‘tracers’ to highlight the chemical activity in the blood vessels which is combined with the images obtained from the CT scan.

The aim of this study is to see what processes are occurring in the arteries that supply blood flow to the legs and whether such processes predict the renarrowing of the arteries after the balloon treatment. As such, the use of these scans might better help us predict whether a treatment will work and how long it will work for.

**Why have I been invited?**

You have been chosen because you have been found to have ‘furring up’ (atherosclerosis) of the blood vessels in your legs and you are going to undertake a balloon treatment (angioplasty) as suggested by the surgical team looking after your care.

If you wish to take part *and* you meet all the requirements, you will be considered for the study.

**Do I have to take part?**

No. You should decide for yourself whether you wish to take part or not. We will describe the study and go through this information sheet with you. If you wish to take part we will ask you to sign a consent form to show you have agreed to take part. If you decide to take part, you can withdraw from the study at any time even if you have signed the form. You will not have to state why you have made that decision and it will in no way affect your future care.

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

Any results that may be useful in making decisions about your care will be passed on to the doctors looking after you. There may be **no** direct benefit for you in taking part, but the results of this study will help our understanding of atherosclerosis in patients with problems with the arteries in the legs.

**Will taking part interfere with my treatment?**

No. Scan appointments will be arranged at your convenience and any treatment you need will take priority.

**What will happen to me if I take part?**

If you decide to take part, we will ask you to initially come to Addenbrooke’s Hospital on two separate days for a scanning session prior to your angioplasty. We would aim to time these scanning sessions within five days of each other. You will be reimbursed for any travel expenses incurred in attending these sessions.

At each session your legs will be scanned on a combined PET/CT machine. At the first session we will also draw a number of blood samples before scanning takes place to measure cholesterol and inflammation levels in the blood stream. We will ask you to fast for 6 hours prior to the scans and we will endeavour to perform the scans first thing in the morning. You are not eligible for recruitment if you take insulin for diabetes but you are okay to take part if you just take tablets for diabetes.

The scans will involve giving you a *radioactive tracer.*  A cannula (thin plastic tube) will be inserted into a vein in your arm. The tracer will be injected through the cannula and we would then aim to do the scans 2 hours after the injection of the tracer. The technique is so sensitive that only a very tiny amount of the radioactive tracer is required. During the scan, you will be asked to lie flat on a bed on your back within the CT machine (which is shaped like a large doughnut). Once you are settled comfortably, we will ask you to stay in the same position for the time it takes to do the scan (between 15 and 60 minutes).

You are strongly advised not to go to work on the day of your scan. We also recommend that you don’t have close contact with pregnant women or young children for 8 hours after the scans, as the tracer takes a little while to leave your body (it comes out through the urine). You are encouraged to drink plenty of fluids of any type as this will help flush the tracer through your kidneys.

On the first of these days, you will also undergo an ultrasound scan of both your legs to look at the blood flow through your arteries.

Most people with this condition have already had a standard CT scan to specifically look at the arteries within the legs (a road map of the arteries of the legs to plan treatment). If you have not had one of these scans we will also need to perform a further CT scan with contrast dye injected through the cannula in your arm. We will be able to inform you about this when we first see you.

Following your angioplasty, we will then ask you to return to Addenbrookes after 6 weeks to repeat the two scans on the PET/CT machine and also to repeat the ultrasound of the arteries to look at the blood flow through the arteries in both your legs. Again this will require you attending the hospital on two separate occasions for between 4 and 6 hours on both occasions and we will again try to perform the two PET CT scans within 5 days of each other.

Finally, you will be required to attend Addenbrookes on one further occasion at one year after your angioplasty treatment. At this visit we will only be performing the ultrasound of the arteries to look through the blood flow through the arteries in both your legs. This visit will last less than one hour.

These visits are in addition to the out patient appointments that you will have with your named consultant as part of the usual NHS care you would receive after your angioplasty.

In summary, taking part in this research study will require 5 extra visits to Addenbrookes, 4 of them requiring a 4-6 hour stay and the final visit will be of less than one hour.

The entire research project will be carried out over 3 years and it is expected that you will be involved for a maximum of 14 months (from signing the consent form to the last research based assessment which occurs a year after your treatment).

If you decide to take part, we will need you to follow these specific instructions:

Smoking You can participate in this study if you are a smoker. However, you will not be allowed to smoke whilst in the hospital.

Food and Drink You will need to *fast for 6 hours before the PET scan with the tracer*. You do not need to fast before the other scans.

You must not consume *alcoholic drinks or anything containing caffeine* (such as tea, coffee, cola, high caffeine energy drinks [e.g. Red Bull] or chocolate), for *24 hours* before each study session.

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

The PET/CT scans use radioactive tracers, which break down very quickly and disappear from the body within a few hours being passed out of the body through the urine. There is also a small radiation dose from the CT part of the scan.

The total radiation dose (26.7 milliseiverts) for both the PET/CT scans is comparable to the natural background radiation you could expect from living in East Anglia for 10 years. The radiation dose will be given at two distinct time points, approximately two months apart and the total extra radiation dose is almost equivalent to that which would be delivered by a single CT scan of the chest, abdomen and pelvis.

This radiation dose carries an additional risk of cancer of 1 in 900, but this should be compared to the overall risk of death from cancer of about 1 in 4 over an average person’s lifetime.

Although it is extremely unlikely that an allergic reaction or other side effect will occur, there are facilities in place within the PET/CT Units and at the hospital to deal with them. Placing a cannula (small plastic tube) into a vein can cause some discomfort and very occasionally can lead to infection but this is unlikely in the short time it will be in place. Some people can also get bruising at the site where the cannula is inserted. This procedure is performed regularly in the hospital and is generally very safe. The cannula will be inserted just before the scan and will be removed immediately afterwards. A new cannula will be put in for the next scan, as it will be on a different day.

There is a small chance that your scan may show something abnormal that you did not know about. Any incidental findings will be communicated to you directly and with your consent we will also inform your GP.

**If you have private medical insurance, you should check with the company before agreeing to take part in the study to ensure that your participation will not affect your insurance.**

**Will my taking part in the study be kept confidential?**

Yes, all information gathered about you will be handled in confidence. We will not inform anyone of your participation in the study without your consent. The detailed information on this is given in Part 2.

**Will my GP be informed?**

We will not inform anyone of your involvement in the study without your consent. We would recommend allowing us to inform your General Practitioner, however.

**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 a decision.**

**PART 2**

**What will happen if I don’t want to carry on with the study?**

You can withdraw from the study at any time. If you withdraw from the study, any stored tissue samples that can still be identified as yours will be destroyed if you wish, but we will continue to use the data collected before your withdrawal. We would also like your permission to continue to use the information we have gained in the study if anything was to happen that affected your ability to agree to take part, such as a stroke.

**What if I am unhappy with things or something goes wrong?**

General advice about taking part in research is available on the NHS website (http://www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx)

If you are unhappy with your participation in the study, you can also seek advice from the Patient Advice and Liaison Service (PALS) based at Addenbrooke's Hospital. They have an office next to the hospital's main entrance and are also available by telephone (01223 216 756) and email on pals@addenbrookes.nhs.uk.

If you have any concerns, questions or complaints regarding the study, please contact **Mr Patrick Coughlin** or any other member of the team by post, telephone, or e-mail using the contact details below.

**Are there compensation arrangements if something goes wrong?**

If 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, then you may have grounds for a legal action for compensation against Addenbrooke’s Hospital (Cambridge University Hospitals NHS Foundation Trust) but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you. We are not covered for non-negligent harm.

**Who is organising and funding the research?**

This research project is organised by the Vascular Imaging / Vascular Surgery group at Addenbrooke’s Hospital, under the supervision of Mr. Patrick Coughlin. Funding for this study has come from the Circulation Foundation.

**Who has looked at and approved the study?**

All research in the NHS is looked at by an independent Research Ethics Committee to protect your safety, well-being and dignity. This study has been reviewed and given a favourable opinion by the NRES Committee East of England - Cambridge East Research Ethics Committee. The Administration of Radioactive Substances Advisory Committee has also granted permission for this study to be performed.

**Confidentiality – who will have access to the data?**

The imaging data will be stored on a secure network and only members of the research group will have access to the data. Once the data is collected it will be assigned a unique number so that you will not be identifiable from it. It is possible that the data may be used by researchers working with the team for other similar ethically approved research studies, where the same standards of confidentiality will apply. It may also be disclosed to researchers working outside the European Union, when that person is working in close collaboration with the research team. In that case the person has signed a Code of Conduct guaranteeing that the data will be kept confidential and securely.

Only members of the Research Group will have access to the data from analysing tissue taken at surgery.

**What will happen to the results of the research study?**

Imaging data will be kept securely possibly indefinitely in the NHS data archive in accordance with good research practice.

Scientific data generated by tissue and data analysis will be kept for the duration of the study until publication and for a maximum of 15 years.

Study results will also be used to write reports and scientific papers, which may be published in medical journals but you will not be identified in any report or publication. If you wish, the results of the study can be communicated to you in written form (either a concise summary and/or the scientific paper itself)

**What will happen to any samples I give?**

The blood sample taken for cholesterol and inflammation / calcification levels will be sent to the Biochemistry Laboratory for analysis as well as being stored for future analysis. Any blood samples taken during the scanning sessions will be analysed immediately and then discarded in the appropriate manner. They are not labelled or stored.

**Will video/audio tapes be used?**

No.

**Contacts for further information**

**Mr. Patrick Coughlin Tel: 01223 274430**

Mr. Coughlin is a Consultant Vascular Surgeon. He can provide further information regarding the study, and may be present to obtain your signed consent if you decide to participate. A member of his team will be present for your visits to the PET/CT Department, will examine you and will take any blood samples necessary.

Email:Patrick.coughlin@addenbrookes.nhs.uk

Address: Box 201

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**Mr. Mohammed Chowdhury Tel: 07783 028033**

Mr. Chowdhury is a Vascular Research Fellow and surgeon in training. He can provide further information regarding the study, and will obtain your signed consent if you decide to participate. He will be present for your visits to the PET/CT Department, will examine you and will take any blood samples necessary.

Email:mohammed.chowdhury@addenbrookes.nhs.uk

Address: Box 201

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*Thank you for considering taking part in this study. If you require any further information, please do not hesitate to contact us, we will be pleased to help you in any way we can.*