PANTHER – PAD STUDY

Title of Study: Personalised antiplatelet therapy for patients with peripheral arterial disease (PANTHER – PAD).

Chief Investigator: Professor Matthew Bown

Participant Information Sheet

What is the purpose of the research Project?

This research study aims to find out more about patients with poor leg circulation, what happens to them and what is the best treatment for them. We would be taking blood samples to assess blood clotting function and whether they were resistant to aspirin and clopidogrel. This will allow us to treat patients better in the future.

Why am I being asked to take part in this research?

You have been invited to take part in this research because you have recently attended a vascular clinic or have been admitted to the vascular ward at the Glenfield Hospital with problems with leg circulation.

Before you decide whether or not 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 this information sheet carefully and discuss with others if you wish. It is up to you to decide whether or not to take part. If you decide to take part you are still free to change your mind at any time during the study. That decision will not affect the care you receive in any way.

If there is any part of this information sheet that you do not understand, or require further information about, please contact us and we will be happy to answer any questions you have. Our contact details are on the last page.

Do I have to take part?

No. It is entirely up to you to decide. If you do not want to take part that is OK. Your decision will not affect the quality of care you receive. If you do decide to take part you are free to withdraw at any time, without giving a reason, by contacting the research team. If you do change your mind and withdraw, we will keep and use the data we have collected up to that point.

What will happen to me if I take part?

The study will involve collecting information from your medical records. This information will include:

- Your age,
- Your gender,
- The medications that you are on,
- Your smoking habits,
- Your past medical history,
- Your symptoms, and extent of your vascular disease.

In addition to the standard care you receive during your attendance, we will ask you some further questions and draw 20ml of blood from an arm vein, for additional blood tests. These tests will tell us if your body can process the tablet you are given to prevent your blood from being sticky or whether you are not sensitive to it. All the blood tests will be taken by a trained member of the research team at the Glenfield Hospital. This will be done before your procedure. The discomfort experienced by the blood test will be no different to that of blood tests you have at your GP surgery.

At 6 and 12 months we will follow-up your progress, either face-to-face at a clinic appointment, or if you find it difficult, over the phone. During these follow-up meetings, that will take no more than 15 minutes, we would like to find out how well you have been, and whether you have had any new medical problems, such as a stroke/mini stroke, heart attack, or required any additional surgery.

Summary of Involvement:

Visit Name	Details
Baseline	Patient information and medication history. Blood test to see if you are sensitive to the antiplatelet tablets that you are on.
6 months	15 minute follow-up, either face to face or in clinic
12 months	15 minute follow-up, either face to face or in clinic

What will happen to the samples I provide?

Samples that you provide will be stored in a secure facility at the University of Leicester. The samples will be labelled with your 'study ID' and not your name, and the date they were collected.

At the end of the study, with your permission, we would like to keep your remaining samples (in their pseudonymised form) for use in future ethically approved research including DNA analysis.

For this type of study, we will store the anonymous research data and any research documents with personal information, such as consent forms, securely at the University of Leicester. If you give us permission to retain your samples for future research, it is necessary to retain your consent form until the samples have been depleted or destroyed, or if you withdraw your permission.

The Human Tissue Authority is the regulatory authority responsible for the oversight and

inspections of human tissue storage in the UK after a study has concluded. We require your consent form to comply with the Human Tissue Authority to ensure we have obtained your permission to retain the samples beyond the life of this project. Your consent form would be stored independently from your pseudonymised samples to ensure your samples remain anonymous to researchers that may use them in the future.

What are the possible benefits of taking part?

Although you would not receive any extra benefit from taking part, research like this helps to continually improve the treatment and care provided to all patients now and in the future.

What are the disadvantages/risks?

There are no extra risks involved in taking part in this research. You will not be asked to try any new treatments. If you choose to participate in any of the additional assessments the main disadvantage is that you will have to give up some of your time. You may experience bruising from when blood samples are taken

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak with a member of the study team who will do their best to answer your questions. If you have concerns about any aspect of the way you have been approached or treated during the course of the study, you may wish to contact the hospital's Patient Information and Liaison Service (PILS). Contact details for the research team and PILS office can be found below. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure. Details can be obtained from the PILS office or from the hospital.

It is very unlikely that you would be harmed by taking part in this type of research study. 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 University of Leicester but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).
If you wish to make a complaint, or require advice about taking part in the study you can contact the <insert NHS PILS information during localisation>.

What will happen to the information collected about me during the study?

Your medical information will be kept strictly confidential by the researchers. The researchers will only collect as much information as is needed for this research and that information will be anonymised before being transferred to the University of Leicester. Your consent form will be sent securely to the University of Leicester and will be stored separately from your research data and samples with limited access to restricted personnel, the research team will not be able to access the consent forms.

We will use your contact details to arrange the follow up visits. On the consent form, you can also be informed about the results of the trial. If you consent for this to happen, we will

store your contact details securely, separately from your survey form and clinical information, and we will only use them for the purposes you have chosen. Your contact details will be destroyed once they have been used for the purpose that you have agreed to. We take confidentiality very seriously. As we will be using information from you in order to undertake this study, the University of Leicester will act as the data controller for this study. This means that we are responsible for looking after your information, keeping it confidential and using it properly.

You should be aware that we have a professional and ethical duty to act on concerns for your safety and welfare. If we identify welfare issues, such as deteriorating illness or concerns of abuse, we may need to report these to your GP, your hospital team, or social services. We will tell you if we do this. We will also inform you and your GP of any incidental findings.

How will we use information about you?

We will need to use information from you (contact details) and from your medical records (as detailed above) for this research project. 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.

We will also inform your GP of your participation in this study.

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.

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

- at www.hra.nhs.uk/information-about-patients/
- on the following website: www.le.ac.uk/patient-gdpr-guidance
- by asking one of the research team
- by contacting us via the e-mail address or phone number at the end of this sheet
- by contacting the University's Data Protection Officer and In-House Commercial [insert name], University of Leicester, University Road, Leicester, LE1 7RH please email DPO@le.ac.uk or ring 0116 229 794.

8. What will happen to the results of the study?

We will present our findings at scientific meetings and publish in medical research journals.

All these results will be totally anonymous and it would not be possible to identify any research participants. The data collected as part of this study may be used, in part or whole, for the writing of educational projects.

What should I do if I want to take part?

You will be asked to complete an Informed Consent Form and to opt-in to a variety of research options by placing your initials within the Yes or No box. This will confirm you understand how your data will be processed, protected and reviewed for research purposes.

Who is organising and funding the research?

The study is being run by investigators based at the Department of Cardiovascular Sciences at the Glenfield Hospital and is sponsored by the University of Leicester. This research is being funded by a charitable donation, by the Van Geest Heart and Cardiovascular Research Fund. The researchers are not being paid for including participants in the study.

Who has reviewed the research project?

All research that involves NHS patients or staff, information from NHS medical records or uses NHS premises or facilities must be approved by an NHS Research Ethics Committee before it goes ahead. This research was approved by Health Research Authority and the XXX Research Ethics Committee. Approval means that the committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits and that you have been given sufficient information on which to make an informed decision.

The study has also been reviewed by the University of Leicester.

Thank you for taking the time to read this information and consider taking part in this study.

Further information: You can ask a member of the research team or your healthcare professional any questions you may have about the study.

Contact Details:
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