Participant Information Sheet (PIS)

Title of the study: SHOCkwave lithotripsy for **C**alcified plaques in patients with peripheral arterial disease: a pragmatic registry with in-depth automated plaque analysis – the SHOCC study.

Chief Investigator: Mr Athanasios Saratzis (University of Leicester, Department of Cardiovascular Sciences)

Principal Investigator <insert local site details>

Invitation

You are invited to take part in a research project. Before you decide whether or not you would like to take part, we would like you to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and talk to others about the study if you wish. You can ask us, or your doctor, questions at any time.

Background

Peripheral Arterial Disease, (commonly referred to as PAD), is the narrowing of one or more of the arteries (blood vessels) in the body. It mainly affects the arteries that take blood to the legs, and affects 20% of people over the age of 60. People with PAD can experience leg pain, ulcers or gangrene. This often requires treatment to improve the leg circulation, and prevent an amputation of the leg. The most common treatment for PAD is an angioplasty. This is where a doctor places a balloon in the affected arteries to widen them and improve blood flow. However, if there is a lot of calcium in the arteries (which is common in PAD), it makes them hard. This can make it difficult for the surgeon to inflate the balloon that is placed inside the artery. A new procedure has been developed called intravascular lithotripsy, which we hope will improve the success of an angioplasty, and ultimately reduce amputations in people with PAD. This new treatment uses a different balloon that emits ultrasounds in order to break down the calcium in the artery, allowing the doctor to stretch the artery more efficiently during the angioplasty. The intravascular lithotripsy procedure occurs immediately before the traditional angioplasty procedure and forms part of the same operation.

Aim

The main aim of this study is to assess how well this new treatment, treats arteries in the legs of people with PAD that have lots of calcium in them. It will also help us find out if it can prevent amputations and improve outcomes for people with PAD.

Why have I been invited?

We have invited you to take part because you have narrowed or blocked arteries in your leg(s), a condition called PAD, which your doctor is planning to treat using an angioplasty procedure which involves intravascular lithotripsy.

What would taking part involve?

This study will not change the medical care that you would normally receive. You will come to hospital for your routine appointments. You will also have the intravascular lithotripsy

procedure as planned by your doctors. At the same time, we would like your consent to be able to access your medical records as part of this study. This will allow us to collect information relating to the time period before the intravascular lithotripsy and up to six months after your discharge from hospital. A list of all the information we would like to obtain from your records can be found in the section below 'How will we use information about you?'
Further, we would like you to complete a questionnaire about your quality of life, once during your appointment before the intravascular lithotripsy and then after 6 months. The questionnaire will take approximately 10 minutes to complete.

Do I have to take part?
It is your choice if you wish to take part in this study or not. You will be given at least 24 hours to decide if you wish 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 later change your mind, you are still free to withdraw at any time, without providing a reason and without your medical care or legal rights being affected. You will still have the intravascular lithotripsy and angioplasty as part of your routine NHS care if you decide not to take part in this study.

Additional sub-study (only patients from Glenfield Leicester Hospital)
We are inviting a small number of people recruited from Leicester hospitals to also take part in a small sub-study, which involves one extra CT scan within three days of your procedure. This scan is additional to routine NHS care. This scan is focussed on the area of your legs that your procedure was done on. The aim of this additional CT scan is to find out how the intravascular lithotripsy procedure has affected the plaque in your artery. The additional CT scan does involve some addition radiation. We will make sure that the additional radiation will be as low as possible by focussing the CT scan only on the area where the intravascular lithotripsy was used. You can take part in the main study only, without taking part in the sub-study.

Special procedures in place during the COVID-19 pandemic
Ensuring safety from COVID-19 is a major priority of the study team. Best practice safety measures will be implemented in line with guidance from the University of Leicester and local NHS Trust policies. Taking part in this study will not require any additional visits to the hospital and will not increase your length of stay following your procedure.

Expenses and payments
You will not receive any payment or expenses to take part as this study will not require any additional visits to the hospital.

What are the possible benefits of taking part?
If the study is successful, this may benefit thousands of patients across the UK and may change the way that PAD is treated. If intravascular lithotripsy is shown to be a better treatment for PAD, it could bring significant cost savings to the NHS as the treatment of these health problems is very expensive.

What are the possible risks and disadvantages of taking part?

Standard Participant - those not taking part in the sub-study

If you take part in this study you will not undergo any additional procedures above and beyond routine NHS care. The only additional task you will be ask to undertake is the completion of the quality of life questionnaire which may take up an additional 10 minutes of your time.

Sub-group Participant

If you take part in the sub-study you will have an additional focussed CT scan within 3 days of the procedure. This involves some radiation and it is an additional procedure which you would not have had if you did not take part in the sub-study. A CT uses ionising radiation to form images of your body and provide treatment. Ionising radiation may cause cancer many years or decades after the exposure. We are all at risk of developing cancer during our lifetime. Around 50% (one in two of us) of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Taking part in this study may increase the chances of this happening to you to about 50.1 % i.e. increase by 0.1% or one in a thousand.

What if something goes wrong?

It is unlikely that you will be harmed by taking part in this research study. However, if you wish to complain or have any concerns about the way you have been approached, treated or the way your information has been handled, you should ask to speak to ***<name of Principal Investigator (PI) at site>.*** Their contact details are:

<Insert PI contact details>

If you remain unhappy about the way researchers have handled your information you should contact the University's Data Protection Officer and In-House Commercial Lawyer (Elisabeth Taudi), University of Leicester, University Road, Leicester, LE1 7RH please email ias@le.ac.uk, or ring 0116 229 794. Alternatively you can contact the University of Leicester's Research Governance Office via RGOsponsor@le.ac.uk and we will do our best to answer your questions.

If you remain unhappy and wish to address your concerns or complaints on a formal basis, you should contact:
Patient Information and Liaison Service, <**Insert local PALS contact details>**
Or
Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

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.

Will my taking part in the study be kept confidential?

The University of Leicester is the sponsor for this study based in the United Kingdom. We will be using information from you 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. Any information about you that leaves the hospital will be pseudo-anonymised which means that it will be given a unique code number in place of your name. The information we obtain from your medical records will be used for this research only and not for any other purpose. Your medical records and/or data may be accessed by authorised individuals from the Sponsor, regulatory authorities and the host NHS organisation for monitoring and audit purposes.We have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

On the consent form, you can also choose to be informed about the results of the study. If you consent for this to happen, we will store your contact details securely, separately from your 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.

Paper based pseudo-anonymised study records will be stored locally in locked filing cabinets within the locked study office. Electronic pseudo-anonymised records will be stored in a secure encrypted database with restricted access on a University of Leicester server. Other participating NHS sites can also assess this database, but their access is strictly controlled. All study documentation will be retained in a secure location locally during the conduct of the study. All research data generated by the study will be pseudo-anonymised and retained in a secure location for six years after the end of the study at **<local site name>** as per the University of Leicester policy. Following that, forms and data will be destroyed based on NHS and Good Clinical Practice principles.

How will we use information about you?

We will need to use information from you and your medical records for this research project. Where available this information will include your:

- Contact details
- Name - baseline
- Age in years (age) - baseline
- Sex - baseline
- Height – baseline and 6 months
- Weight – baseline and 6 months
- Blood pressure - baseline and 6 months
- Smoking status – baseline and 6 months
- Medical history – baseline
- Heart attacks and strokes – discharge, 30 days and 6 months
- Medications – baseline, 30 days and 6 months
- Routine blood tests - baseline and 6 months
- Diabetes status – baseline and 6 months
- Ankle brachial pressure index – baseline, discharge, 30 days and 6 months
- Quality of life questionnaire – baseline and 6 months
- CT scan result – baseline and at any point a new CT is required

- Ultrasound scan result – baseline and at any point a new CT is required
- Information relating to your hospital stay – discharge
- Information relating to any additional surgeries – 30 days
- Treatment for PAD in the 6 months post intravascular lithotripsy angioplasty procedure – 6 months
- Surgery details (duration of intravascular lithotripsy application per site, number and size of intravascular lithotripsy balloons used) - discharge
- Additional treatments which occurred alongside intravascular lithotripsy - discharge
- Duration of whole surgical procedure – discharge
- Complications after surgery - discharge
- Operators performing the procedures - discharge
- Volume of contrast (x ray dye) used during the procedure. - discharge

People will use this information to do the research or check your records to make sure 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.

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. Please inform the Principal Investigator ***<name of PI>*** if you wish to withdraw (contact details at the end of this sheet).

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

You can find out more about how we use your information

- At www.le.ac.uk/patient-gdpr-guidance or www.hra.nhs.uk/information-about-patients/
- by sending an e-mail to **<study contact details>**
- by contacting the University's Data Protection Officer and In-House Commercial Lawyer (Elisabeth Taudi), University of Leicester, University Road, Leicester, LE1 7RH please email ias@le.ac.uk, or ring 0116 229 794.

With your consent, if you would like us to keep your details for future research, we will save them on a secure database at the University of Leicester. You can have your details removed at any stage by contacting the Principal Investigator.

Will the use of my data meet GDPR rules?

GDPR stands for the General Data Protection Regulation. This research will follow the GDPR rules based on a law called the Data Protection Act. All research activities during this study will follow UK laws and rules.

When designing this research and during the conduct of the study, the views of patients and ordinary members of the public have been, and will be, taken into account. We will take all

necessary steps to protect the privacy of the people who take part. An NHS research ethics committee will have checked this before the research starts.

What will happen to the results of this study?
Upon study completion, updates and lay summaries will be prepared with the help of patients prior to lay dissemination on the internet (through social media, study webpage, NIHR Biomedical Research Centres online resources) and via patient leaflets. The results will be published in medical journals and presentations as well as being summarised in a report to the funder, nobody will be able to identify you from the reports which we write. If you would like to receive a summary of results, you will be asked to indicate this on your consent form. Direct patient or stakeholders' quotes will not be published. No identifiable or sensitive data will be published.

Information collected from this study will inform a larger research study in the future, which will explore whether the addition of intravascular lithotripsy is better than angioplasty alone.

Who is organising and funding this study?
The study is funded by Shockwave Medical, Inc, the company that designed the intravascular lithotripsy procedure. The funder has no involvement in the research design or analysis of the data. The funder will not at any point be allowed access to your data and information.

How have patients and the public been involved in this study?
The protocol and the study design have been reviewed by four patients who have PAD and have previously undergone at least one angioplasty. The study design and the wording of the protocol, including the lay summaries, was found appropriate.

Who has reviewed this study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by **XXXXXX.** The study has received sponsorship from the University of Leicester and NHS organisations have also been able to review and subsequently approve the study.

Commercial exploitation.
The findings of this research will not be explored commercially.

Who to contact for further information
You can ask a member of the research team or your healthcare professional any questions you may have about the study.

<insert local PI name and contact details>

Chief Investigator contact details:

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University of Leicester, Department of Cardiovascular Sciences

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Groby Road
Leicester
LE3 9QP
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Telephone: 0116 252 4875

What happens next?

You will be approached at either your clinic visit or during your ward stay in hospital by a member of the research team in order to discuss any questions you might have. If you would like to take part in this research you will then be asked to sign an informed consent form. You will then be able to take part in this research.

Thank you for reading this information and for considering taking part in this research