PARTICIPANT INFORMATION SHEET

Title of Study:
Evaluation of optoacoustic imaging and photoplethysmography in patients with foot ulcers: A cross-sectional pilot study (OAI-1)

Chief Investigator's name: Prof. Christian Heiss **IRAS ref:** 331195

PLEASE KEEP A COPY OF THIS INFORMATION SHEET FOR YOUR RECORDS

Section 1: Taking Part

We would like to invite you to participate in this research study at East Surrey Hospital, part of Surrey and Sussex Healthcare NHS Trust. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please discuss the study with others if you wish. We will go through this information sheet with you and answer any questions you have. You can also contact us using the contact details at the end of this information sheet.

What is the purpose of the study?

The aim of this study is to see if new optical diagnostic tests called optoacoustic imaging (OAI) and photoplethysmography (PPG) can provide clinical information in addition to standard tests currently offered by NHS that can help predict wound healing.

OAI uses laser light to get information about tissue in the body. It can tell us how much blood and oxygen is in the tissue around a wound. Measurements on the lower legs and arms will serve as reference to help work out how much lower the oxygen around the wound is, compared with other parts of your body. More information is available on the manufacturer's website: https://ithera-medical.com

PPG is a technology that uses a light source and a detector at the surface of skin to measure blood flow, and is used in many smart watches now, for example to measure heart rate. The amount of reflected light tells us how much blood flow reaches the skin around the wound. More information is available on the manufacturer's website: https://shimmersensing.com/

We plan to use OAI and PPG to take non-invasive measurements using light on your feet, legs and arm together with standard measurements of the blood pressure at your ankle and toes. Finally, we want to see if the new measurements can predict how your wound develops and if it can better tell us which wounds will heal and which will not.

Why have I been invited to take part?

You are invited to participate in this study because you have a non-healing wound on your foot and you have been referred for specialised assessment and treatment at East Surrey Hospital. We expect that around 40 patients will participate in the study.

Do I have to take part?

No, participation is voluntary and you do not have to take part. We will describe the study in this information sheet and will give you at least one day until your scheduled routine hospital appointment to read this, so you can decide whether you wish to take part in this study.

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

If you decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form to confirm your agreement to participate. You will be given a copy of the consent form to keep.

On the day of your routine hospital appointment we will perform OAI and PPG measurements using two different scanning devices on the skin of your feet, lower legs and arms. Both techniques are entirely painless, like shining a flashlight on the skin, and there are no known side effects. You may feel slight pressure when the sensors are put on your skin. Your appointment may take about 30 minutes longer than if you did not take part in the study. You will be asked to wear safety goggles during the OAI measurements.

We will compare the new measurements with measurements taken as part of your standard care. Standard care measurements usually include ankle-brachial pressure index, toe pressure and vascular ultrasound. The ankle brachial pressure index measures the blood pressure in the leg and toe pressure measure the blood pressure in the toes. The vascular ultrasound scan is a 'gel scan' of your arteries in the leg.

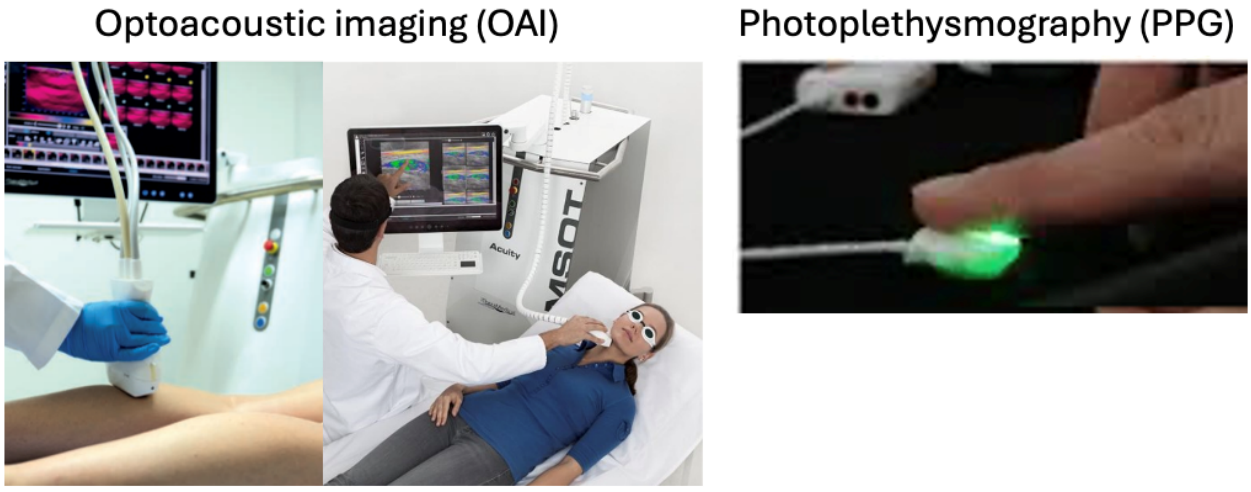

Figure 1: Images of optoacoustic imaging (OAI, left and middle) scan and photoplethysmography (PPG, right) sensor. The OAI images are taken just like a 'gel scan' on the arm and legs (left) and require wearing of laser protection goggles (middle). PPG signals are measured with green light on your fingers and feet.

If you require a procedure called 'angioplasty' to unblock your leg arteries, this will be booked as a standard procedure in our radiology department and you will spent the day in the daycase unit. We will perform the OAI and PPG measurements during that time in the day case unit before and after the angioplasty. This will not make your hospital stay any longer than it would usually take. This will show if OAI and PPG can detect improvements in blood flow as a result of the 'angioplasty' procedure.

Some participants will have their study measurements repeated (by the same doctor and then a different doctor) to see if readings vary if time allows; these study participants may need to stay 5-10 min longer in clinic.

We will collect information from your healthcare records at study start during your clinical appointment and store them in a database in a way only the study team can identify you. After 1 year we will review your records again and see if the ulcer has healed, and to check your general health status. In case your healthcare records are incomplete, we may call you to briefly ask how you are doing.

You can find out more about how we will use your data and your choices in section 2.

What happens if I do not want to take part or if I change my mind?

Deciding not to take part or withdrawing from the study will not affect the healthcare you receive. You are free to withdraw from the study at any time, without giving a reason. Data already collected will be retained.

What are the possible benefits in taking part?

As we do not know for sure if these measurements are helpful, we will not use the information to change how we will treat you. There may be no direct benefit to you from taking part in the study but your participation may provide a better understanding of why some wounds do not heal and may help develop a diagnostic test and personalised treatment approaches in the future. As the investigations are performed on the same day as your routine care appointment we will not offer any compensation or reimbursement.

What are the possible disadvantages and risks of taking part?

The only disadvantage to taking part in the study is that it may take some of your time, for which we are extremely grateful, as your appointment may be 30-40 minutes longer. The investigations are non-invasive. Nevertheless, OAI requires laser light to look at tissue, therefore the use of laser safety goggles is necessary. These goggles would only need to be worn during the OAI, which should take 2-5 minutes.

Who is organising and funding the research?

This study is sponsored and organised by the University of Surrey and led by Professor Christian Heiss, Consultant Vascular Physician, Surrey & Sussex Healthcare NHS Trust, East Surrey Hospital.

The OAI device being used for the study is provided by iThera Medical (https://ithera-medical.com) manufacturer of the device. iThera has provided a grant to contribute to running of the study, will provide training for staff and will support with analysing data but will not have access to personal data of study participants.

In addition, the analysis of PPG signals is partly funded by research grants of the Medical Research Council.

Will my participation be kept confidential?

We are responsible for making sure your participation is kept confidential and any data is kept secure and used only in the way described in this information sheet.

All information for this study will be held securely and treated as strictly confidential according to NHS policies and in accordance with the principles of the Data Protection Act 2018. No directly identifiable data will be stored outside the hospital either in paper or electronic format.

De-identified images will be transferred to the company who make the OAI device, so they can help with analysing the data. De-identified data will be transferred to the University of Surrey for the statistician to help with analysing data. No identifiable data will be transferred outside the hospital trust.

Identifiable data will be collected in a database and stored on a hospital secure server in a password protected project file accessible only to named individuals working on the study. Each study participant will be assigned a study number (a random combination of letters and numbers), and this will be linked to the de-identified data in the secure database.

The OAI images and PPG data will be recorded only with the study number assigned to the participant. It will not be possible to identify you from the images.

If you consent to take part, your information may be looked at by individuals from the University of Surrey sponsor, Surrey and Sussex Healthcare NHS Trust and/or regulators to make sure that the research is being done properly and who will treat your data in confidence.

Will my data be shared or used in future research studies?

We would like your permission to share de-identified anonymised research data with collaborators and publish them in a public repository or as part of a scientific publication or presentation.

What will happen to the results of the study?

We will produce a final report summarising the main findings. This research and findings may be published in scientific journals, presented at conferences and published on relevant websites. You can contact the study team to find out the results of the research. No individual participants will be identifiable from any report or publication placed in the public domain. If you would like to receive a lay summary of the results or copy of scientific publication, we ask that you provide an email or address that we need to store until the end of the study.

Who has reviewed this study?

This research study has been reviewed by an independent group of people, called a Research Ethics Committee. This study was reviewed and given a favourable ethical opinion by the xxxxx NHS Research Ethics Committee.

This completes Section 1 of the Information Sheet.

If the Information in Section 1 has interested you and you are considering participation, please continue to read the additional information in Section 2 and 3 before making any decision.

Section 2: Your personal data

What is personal data?

'Personal Data' means any information that identifies you as an individual. We will be collecting and using some of your personal data that is relevant to the study and this section gives information on that. This personal data collected will include your name, email address, phone number, NHS number, and date of birth, which is regarded as 'personal data' and health data including your medical history, medication, comorbidities, demographics, which is regarded as a 'special category personal data'.

Who is handling my personal data?

The University of Surrey has the legal responsibility for the study and will act as the 'Data Controller'. The trust's research team at East Surrey Hospital process your personal data on behalf of the controller and are responsible for looking after your information and using it properly.

What will happen to my personal data?

As a publicly-funded organisation, we have to ensure that when we use **identifiable personal** information from people who have agreed to take part in research, that this data is processed fairly and lawfully. The University of Surrey processes personal data for the purposes of carrying out research in the **public interest** and special category data is processed on an additional condition necessary for **research purposes.** This means that when you agree to take part in this research study, we will use and look after your data in the ways needed to achieve the outcomes of the study.

Your personal data will be held and processed in the strictest confidence, and in accordance with current data protection regulations. Your contact details will be deleted from the research team records one year after the end of the study. Your signed consent form will be kept for 6 years and your anonymised research data will be kept for 10 years after the end of the study.

You can find out more about how we use your information https://www.surrey.ac.uk/information-management/data-protection and/or by contacting dataprotection@surrey.ac.uk .

How will we use information about you?

We will need to use information from you, from your medical records for this research project.
This information will include your name, local hospital number, NHS number, date of birth, contact details held by site. 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.

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.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital and NHS records. If you do not want this to happen, tell us and we will stop.

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?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- By contacting our data protection officers dataprotection@surrey.ac.uk and sash.data.protection@nhs.net
- If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful, you can complain to the Information Commissioner's Office (ICO) (https://ico.org.uk/).

Section 3: Further information

What if you have a query or something goes wrong?

If you are unsure about something you can contact the sponsor (Research Integrity and Governance Office, University of Surrey) or Patient Advice and Liaison Team or research team at the trust for further advice using the contact details at the bottom of this information sheet.

However, if your query has not been handled to your satisfaction, or if you are unhappy and wish to make a formal complaint to someone independent of the research team, then please contact:

Sponsor Team at University:
Assurance Team – Research, Innovation and Impact
University of Surrey
Senate House, Guildford, Surrey, GU2 7XH
Email: assurance@surrey.ac.uk

Patient Advice and Liaison Team at trust:
East Surrey Hospital
Canada Road
Redhill, RH1 5RH
Email: sash.pals@nhs.net Phone: 01737 231958

The University has in place the relevant insurance policies which apply to this study. If you wish to complain or have any concerns about any aspect of the way you have been treated during the course of this study then you should follow the instructions given above.

Who should I contact for further information?

If you have any questions or require more information about this study, you can contact the Chief Investigator directly using the following contact details:

Prof. Christian Heiss
Department of Clinical and Experimental Medicine
University of Surrey
Guildford, GU2 7XH
email: c.heiss@surrey.ac.uk Phone: 01737 768511 ext 1749

Or you can contact the Trust research team at SASH:

Mr. Edward Rippingale Combes
Surrey and Sussex Healthcare NHS Trust
R&D Department A86, Trust Headquarters,
East Surrey Hospital, Canada Avenue,
Redhill. RH1 5RH
Email: sash.clinicalresearch2@nhs.net Phone: 01737 768511 ext 1254

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