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Evaluation of optical imaging in foot ulcer management

Submission date	Recruitment status	[X] Prospectively registered
07/06/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/07/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
20/01/2025	Skin and Connective Tissue Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Non-healing foot wounds (ulcers) are frequent and lead to poor quality-of-life with high risk of amputation and mortality. A major reason for wounds not to heal are blocked arteries in the legs. Currently, the standard test to measure the blood flow in the legs is called ankle brachial pressure index (ABPI) and it requires blood pressure measurement with a cuff at the ankle. However, ABPI is not frequently performed, may miss diagnoses, and does not measure blood flow in the foot where ulcers are.
Optoacoustic imaging (OAI) and photoplethysmography (PPG) are 2 new non-invasive methods that can use light to measure oxygen and blood flow through the skin, but these have not been tested in patients with ulcers.
The aim of the study is to evaluate the value of OAI and PPG in patients with foot ulcers. We hypothesize that OAI and PPG can provide additional important clinical information otherwise not available.

Who can participate?
All patients with foot ulcers scheduled for routine appointments in the multidisciplinary diabetic foot and vascular clinics at East Surrey Hospital.

What does the study involve?
OAI and PPG scans will be performed at several sites along the leg and foot in addition to standard investigations. In those patients that will undergo surgery to improve blood flow as part of usual care, we will repeat all measurements after surgery. We will collect the results of the standard investigations and baseline medical and sociodemographic characteristics and collect 1 year outcome data based on electronic patient records.

What are the possible benefits and risks of participating?
There are no direct benefits to patients. The results will help vascular doctors to evaluate the value of OAI and PPG and if they can provide additional important clinical information otherwise not available.

Where is the study run from?
East Surrey Hospital (Surrey and Sussex Healthcare NHS Trust), Redhill with the University of Surrey (Department of Clinical and Experimental Medicine), Guildford (UK)

When is the study starting and how long is it expected to run for?
December 2023 to March 2026

Who is funding the study?
The study is funded by iThera Medical and Medical Research Council (UK)

Who is the main contact?
Prof. Christian Heiss, c.heiss@surrey.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof Christian Heiss

ORCID ID
http://orcid.org/0000-0002-3212-8995

Contact details
University of Surrey
Leggett building
Guildford
United Kingdom
GU2 7XH
+44 (0)1483 686693
c.heiss@surrey.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
331195

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 68419, IRAS 331195

Study information

Scientific Title

Evaluation of optoacoustic imaging and photoplethysmography in patients with foot ulcers: a cross-sectional pilot study

Acronym
OAI-1

Study objectives
Optoacoustic imaging (OAI) and photoplethysmography (PPG) can provide additional important clinical information that is otherwise not available.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/07/2024, South Central - Oxford C Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8271; oxfordc.rec@hra.nhs.uk), ref: 24/SC/0242

Study design
Single-centre prospective observational cross-sectional pilot study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Foot ulcers

Interventions
Patients with ulcers will be prospectively recruited in the multidisciplinary diabetic foot and vascular clinics. Optoacoustic imaging (OAI) and photoplethysmography (PPG) scans will be performed at several sites along the leg and foot in addition to standard investigations (ultrasound, ABPI, toe pressure) and baseline medical and sociodemographic characteristics. Some patients will undergo surgery to improve blood flow as part of usual care. In these patients, the researchers will repeat all measurements after surgery. They will collect 1 year outcome data (wound healing, amputation, mortality) based on electronic patient records.

Intervention Type
Other

Primary outcome measure
1. Tissue oxygenation and blood flow measured using optoacoustic imaging in feet at baseline (all) and after angioplasty (subgroup that receives angioplasty as standard of care)
2. Blood flow measured using photoplethysmography in feet at baseline and after angioplasty (subgroup)

Secondary outcome measures
1. Ankle brachial pressure index measured using ankle Doppler based estimated ABPI (eABPI) at baseline and after angioplasty (subgroup)
2. Toe brachial pressure index measured using arterial plethysmography with cuff at baseline and after angioplasty (subgroup)
3. Peripheral vascular disease in lower extremity arteries measured with duplex ultrasound at baseline and after angioplasty (subgroup)
4. 1-year outcome (major amputation, death, revascularisation, wound healing) measured using electronic patient records over 1 year

Overall study start date
04/12/2023

Completion date
01/03/2026

Eligibility

Key inclusion criteria
1. Age 18 years or greater
2. Non-healing foot wound for at least 4 weeks despite wound care
3. Scheduled for/referred to routine vascular assessment, multidisciplinary foot team clinic or endovascular revascularisation
4. Willing and able to provide informed consent
5. Vascular ultrasound exam required including Ankle Brachial Pressure Index (ABPI) and Toe Brachial Index (TBI)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria

1. Heart failure New York Heart Association (NYHA) ≥3
2. Systemic inflammation
3. Critically ill, American Society of Anesthesiologists (ASA) IV
4. Extensive foot wounds making OAI scanning impossible
5. No toes to measure TBI
6. Leg wounds or skin conditions preventing ABPI, OAI or ultrasound investigations
7. Participants who are unable to wear the laser safety goggles
8. Tattoos in the field of view for OAI scanner
9. Currently under phototherapy
10. History of photosensitising disease (e.g. porphyria, Lupus erythematosus)
11. Experiencing photo-toxicity associated with currently taking or having taken photosensitizing agents within the previous 72 h (e.g. sulfonamides, ampicillin, tetracycline, doxycycline)
12. Pregnancy

Date of first enrolment
18/12/2024

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Surrey and Sussex Healthcare NHS Trust
Trust Headquarters
East Surrey Hospital
Canada Avenue
Redhill
United Kingdom
RH1 5RH

Sponsor information

Organisation
University of Surrey

Sponsor details
Assurance Team – Research, Innovation and Impact
Senate House

Guildford
England
United Kingdom
GU2 7XH
+44 (0)1483 683490
rigo@surrey.ac.uk

Sponsor type
University/education

Website
https://www.surrey.ac.uk/faculty-health-medical-sciences/research/research-and-innovation-team

ROR
https://ror.org/00ks66431

Funder(s)

Funder type
Industry

Funder Name
iThera

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
European Association of National Metrology Institutes

Alternative Name(s)
EURAMET e.V., European Collaboration in Measurement Standards, EUROMET, EURAMET

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Germany

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results of this study will be submitted for publication in peer-reviewed journals and presented at relevant conferences. The researchers plan to publish the anonymised data in a publicly accessible repository (e.g. UK data archive). This is stated in the patient information sheet and consent form. A lay summary will be sent to participants who indicate they would like to receive this.

Intention to publish date
01/02/2026

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 01	12/06/2024	12/07/2024	No	Yes