ISRCTN17256655 https://doi.org/10.1186/ISRCTN17256655

Terabotics - terahertz robotics for surgery and medicine

Submission date 29/07/2024	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 05/08/2024	**Overall study status** Ongoing	
Last Edited 08/08/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Medical imaging is an important tool in the diagnosis and treatment of skin cancer; however, it carries a small risk of tissue damage due to the use of radiation. Recently, imaging methods have been developed that use electromagnetic radiation at terahertz (THz) frequencies, which are located in a region of the spectrum that make it safe for the in vivo
imaging of humans.
Additionally, there is a pressing need in the surgical field to improve the precision, control and selectivity of skin cancer procedures. For example, in the UK, the incidence of basal cell carcinoma (BCC) has increased by approximately 250% since the 1990s, with 137,000 new cases each year. Delayed diagnosis and incomplete tumour excision are key drivers of patient morbidity, and squander limited surgical resources. If the extent of the tumour could be accurately determined, using THz imaging prior to surgery, the procedure would be faster, and grafts better planned.
In vivo images from a case study of BCC patients in 2004 suggested that THz imaging could detect skin cancer hidden beneath the skin. Spectroscopic studies by Emma MacPherson (Co-investigator) and colleagues showed that the fundamental THz properties of excised tumours are statistically significantly different from healthy tissue, primarily due to changes in water content.
The current study will evaluate the effectiveness of the THz technology during real-world routine surgical procedures for the excision of suspected skin cancers. Whereas the main objective is to explore feasibility, test trial procedures and refine intervention delivery, our secondary objective is to assess whether Skinometry can quantify skin hydration and indicate the extent of BCC skin cancer, melanoma in situ or lentigo maligna pre-cancerous lesions before excision. We will be recruiting patients scheduled for Plastic Surgery at University Hospitals Coventry and Warwickshire, selected based on clinical diagnosis.

Who can participate?
Patients who have been diagnosed with suspected skin cancer (Basal Cell Carcinoma, Melanoma in Situ or Lentigo Maligna) and have been scheduled for a surgical excision of said skin cancer at UHCW.

What does the study involve?
Patients taking part in TERABOTICS will first have their eligibility checked by a member of the clinical research team. Upon confirmation of eligibility and on the day of their surgery, they will have their suspected skin cancer photographed and measured using the Terahertz Scanner. In order to accurately calibrate and compare the Terahertz scans, participants will also have a control and reference area of their body scanned. This is estimated to take no longer than 10 minutes.
Participants' suspected skin cancer will also be measured 'off table' by a member of the research team while their surgery occurs, to be compared to their standard histology results which will be collected once available.

What are the possible benefits and risks of participating?
Patients who choose to take part in Terabotics will not benefit directly, however their contribution will help us improve both the design of a future study, as well as the Terahertz scanner, which may lead to new ways to diagnose and treat various skin conditions. This may mean procedures such as a biopsy may not always be required for future patients.
The risks of taking part are minimal. The Terahertz scan itself is painless, similar to shining a light on the skin. The THz scanner uses very low energy so causes no tissue irritation.

Where is the study run from?
University Hospitals Coventry and Warwickshire NHS Trust (UK)

When is the study starting and how long is it expected to run for?
July 2024 to October 2026

Who is funding the study?
Engineering and Physical Sciences Research Council (UK)

Who is the main contact?
tmu@uhcw.nhs.uk

Contact information

Type(s)
Public

Contact name
Miss Cristiana Huhulea

ORCID ID
https://orcid.org/0009-0000-6444-4987

Contact details
Research and Development
University Hospital
Coventry
United Kingdom
CV2 2DX
+44 24 7696 7476
cristiana.huhulea@uhcw.nhs.uk

Type(s)
Scientific

Contact name
Prof Emma MacPherson

Contact details
Physics Department
Warwick University
Coventry
United Kingdom
CV4 7AL
+44 7749424202
e.macpherson@warwick.ac.uk

Type(s)
Principal Investigator

Contact name
Prof Joseph Hardwicke

Contact details
University Hospital
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX
+44 2476965223
hardwickej@doctors.org.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
335656

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
JH552021, IRAS 335656, CPMS 63816

Study information

Scientific Title
TERAhertz roBOTICS for surgery and medicine

Acronym

TERABOTICS

Study objectives
Primary: to explore the feasibility, test recruitment, trial procedures and refine intervention delivery.
Secondary: to explore if Terahertz skinometry can quantify skin hydration and may indicate the extent of basal cell carcinoma skin cancer, or melanoma in situ or lentigo maligna pre-cancerous lesions, before primary excision.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/08/2024, London - South East Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0) 207104 8202; londonsoutheast.rec@hra.nhs.uk), ref: 24/PR/0849

Study design
Pragmatic non-randomized single-centre feasibility study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic, Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Identifying and assessing the extent suspected skin cancer defined as Basal Cell Carcinoma, Lentigo Maligna or Melanoma in Situ in patients scheduled to have a surgical excision.

Interventions
Participants scheduled to have a surgical excision will undergo the study procedures on the day of their operation, prior to the surgical procedure.
Firstly, participants will have their area of interest photographed on arrival and booking into theatre. They will then be scanned with the THz Skinometer a minimum of three times: once to acquire data from a standard reference area of skin for calibration; once to acquire images of a control area similar to the area of interest, but clinically free from obvious pathology; and lastly they will undergo a scan of the area of interest (suspected skin cancer). A good quality scan will be needed from each area, and may need repeating if the signal acquisition is inadequate.
The area of interest will then be marked with a predefined excision margin with a surgical marker pen, as per normal standard of practice. A standard photograph will again be taken with

the markings in place. Further THz measurements will be taken from the area of interest, these will examine the area of interest and the surrounding skin within and around the surgical marking area. This will take up to 10 minutes.
Following scan acquisition, the surgical procedure will continue as per normal practice, with no further scans on the participant. When the suspected skin cancer has been removed and marked with a surgical marker stitch, it will be passed out to a member of the research team to undertake further THz scans “off table”, prior to being transferred to a prepared specimen pot for transfer to the laboratory for normal histopathological analysis.
The surgical procedure will then continue as normal with suitable reconstruction and clinical follow up planned as necessary.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Terahertz Scanner

Primary outcome measure
Measured at baseline using the screening/recruitment log which clinical research staff will manage, collated safety monitoring reports (AEs/SAEs) and study database output:
1. Number of patients screened, eligible, recruited and withdrawn
2. Patient willingness to participate in the trial
3. Participant tolerance of the device
4. Number of participants with complete datasets

Secondary outcome measures
1. Terahertz scan data and the formal reported histological analysis as part of the standard skin cancer management pathway
2. Histology results collected post-surgery

Overall study start date
07/07/2024

Completion date
31/10/2026

Eligibility

Key inclusion criteria
1. NHS patients attending University Hospitals Coventry and Warwickshire
2. Area of interest accessible for THz scan
3. Aged 18 years and over
4. Suspected skin cancer defined as:
4.1. lesions clinically suspicious for Basal Cell Carcinoma (BCC)

4.2. biopsy proven BBC
4.3. biopsy proven Lentigo Maligna (LM)
4.4. Melanoma in Situ (MiS)
5. Capacity to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Confirmed biopsy proven other skin cancer at the same area of interest
2. Absence of suspected or confirmed skin cancer as described in the inclusion criteria
3. Unable to consent to the study

Date of first enrolment
01/10/2024

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals Coverty and Warwickshire NHS Trust
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation
University Hospitals Coventry and Warwickshire NHS Trust

Sponsor details
University Hospital
Clifford Bridge Road
Coventry
England
United Kingdom
CV2 2DX
+44 24 7696 6195
ResearchSponsorship@uhcw.nhs.uk

Sponsor type
Hospital/treatment centre

Website
www.uhcw.nhs.uk/

ROR
https://ror.org/025n38288

Funder(s)

Funder type
Government

Funder Name
Engineering and Physical Sciences Research Council

Alternative Name(s)
UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, EPSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

We intend to disseminate the findings of our study in the following manner:
• Dissertations
• Reports
• Posters, conference presentations and publications
• Patient and charity groups: PPI members will be regularly briefed about study progress
• Print, broadcast and social media
Study progress will be updated continuously throughout the timeline of the project via the UHCW NHS Trust website. Anonymised results will also be disseminated via clinical trial registries.
The UHCW R&D team, UHCW Innovation team and the University of Warwick (Warwick Ventures) will be informed of all developments where there might be a potential for commercial interest, and in particular prior to any data sharing.

Intention to publish date

01/03/2027

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

Not expected to be made available