

# Can subtle changes in skin hydration be used to help treat dry skin conditions and detect skin cancers?

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| <b>Submission date</b><br>08/02/2022   | <b>Recruitment status</b><br>No longer recruiting                | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>11/02/2022 | <b>Overall study status</b><br>Completed                         | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results            |
| <b>Last Edited</b><br>29/04/2025       | <b>Condition category</b><br>Skin and Connective Tissue Diseases | <input type="checkbox"/> Individual participant data   |

## Plain English summary of protocol

### Background and study aims

Medical imaging commonly involves the use of radiation, such as x-rays, that can give detailed images of internal structures of the body but can carry a small risk of tissue damage due to the radiation involved. As such, the number of x-rays and computed tomography (CT) scans that an individual can have has to be minimised. Methods have recently been developed that make use of electromagnetic radiation for imaging purposes at terahertz (THz) frequencies, the region of the spectrum between millimetre wavelengths and infrared. Terahertz spectroscopic imaging uses low power levels such that adverse effects on tissues are insignificant and is safe for imaging of humans. The terahertz region is between the radiofrequency region and the optical region generally associated with lasers. The aim of this study is to investigate THz spectroscopic imaging as a new and powerful tool for analysing skin properties, termed THz skinometry. The novelty in this project lies in tailoring the instrumentation and algorithms of THz scanning to accurately measure properties of human skin (e.g. hydration levels and skin thickness). The customised non-contact and pressure-controlled contact THz probes developed will be able to do spectroscopic measurements of skin at the molecular level. This will be the first demonstration of THz imaging of skin globally and will facilitate characterisation of skin in a way that has so far not been possible and could lead to a step change in THz technology usage (similar to that currently used in airport security scanners).

### Who can participate?

1. Patients, members of the public or NHS staff aged 18 years and over with dry skin conditions (e.g. eczema, psoriasis, scars)
2. patients aged 18 years and over with confirmed or suspected skin cancer
3. patients aged 18 years and over with clinically benign pigmented skin lesions

### What does the study involve?

Patients with known or suspected skin cancer or benign pigmented skin lesions will have images taken in the clinic before planned skin surgery that will be later compared to the formal histology results after the tumour has been removed. Patients with benign dry skin conditions (eczema, psoriasis, skin grafts, scars etc) will have the water content of their skin measured

before and after the application of emollients in common usage (e.g. E45®, Aveeno®, Doublebase®). This will add to the existing data that has been recorded from healthy non-patient volunteers. This may help to guide patient-specific emollient selection in the future.

What are the possible benefits and risks of participating?

This study will add to the knowledge base to define the appearance of skin cancers and benign pigmented skin lesions under THz skinometry. The findings will not influence the established management that will have been planned in conjunction with a consultant dermatologist or plastic surgeon and the patient.

Where is the study run from?

University Hospitals Coventry & Warwickshire NHS Trust (UK)

When is the study starting and how long is it expected to run for?

March 2020 to March 2023

Who is funding the study?

Cancer Research UK

Who is the main contact?

Cristiana Huhulea (Trial Coordinator), [cristiana.huhulea@uhcw.nhs.uk](mailto:cristiana.huhulea@uhcw.nhs.uk) (UK)

## Contact information

### Type(s)

Scientific

### Contact name

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Principal investigator

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

270335

### **Protocol serial number**

CPMS 50612, IRAS 270335

## **Study information**

### **Scientific Title**

The SINATRA study: SKIN hydrAtion evaluation with TeRAhertz scanning

### **Acronym**

SINATRA

### **Study objectives**

Current study hypothesis as of 20/03/2023:

Terahertz (THz) light can detect subtle changes in skin hydration levels that allow for the assessment of emollients and may lead to personalised medicine for the treatment of dry skin conditions and benign pigmented skin issues. We may also be able to diagnose skin cancer in-vivo (without biopsy) using THz light.

Previous study hypothesis:

Terahertz (THz) light can detect subtle changes in skin hydration levels that allow for the assessment of emollients and may lead to personalised medicine for the treatment of dry skin conditions. We may also be able to diagnose skin cancer in-vivo (without biopsy) using THz light.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 13/10/2021, Yorkshire and Humber – Sheffield REC (NHS Blood and Transplant Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)2071048388; Sheffield.rec@hra.nhs.uk), REC ref: 21/YH/0221

### **Study design**

Non-randomized; Both; Design type: Screening, Device, Cross-sectional

### **Primary study design**

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Current condition as of 20/03/2023:

1. Benign dry skin conditions
2. Known or suspected skin cancer (either confirmed basal cell carcinoma and/or suspected malignant melanoma)
3. Benign pigmented skin lesions (including seborrheic keratosis and others)

Previous condition:

Dry skin conditions (e.g. eczema, psoriasis, scars)

## Interventions

Current interventions as of 20/03/2023:

The SINATRA study will collect preliminary pilot data from patient volunteers in a two-arm proof of concept study. One arm (group A) will consist of 50 patients with benign dry skin conditions (eczema, psoriasis, skin grafts, scars etc) and will compare the water content of skin before and after application of propriety emollients in common usage (e.g. E45®, Aveeno®, Doublebase® etc). This will add to the existing dataset that has been recorded from healthy non-patient volunteers. This may help to guide patient-specific emollient selection in the future. The second arm (group B) will consist of 100 patients with known or suspected skin cancer (incompletely excised basal cell carcinoma [BCC] with histologically proven radial margin involvement or pigmented lesions suspicious of malignant melanoma). Skinometry measurements will be taken in the clinic prior to planned skin surgery and later compared to the formal histology results after the primary (melanoma) or residual (BCC) tumour has been removed. This will add to the knowledge base to define the appearance of skin tumour under THz skinometry. The spectroscopic findings will not influence the established surgical management that will have been planned in conjunction with a Consultant Dermatologist or Plastic Surgeon and the patient.

The patient has a normal clinic visit and subsequent clinical investigations planned as required by the attending clinician. Considering the efforts in the Trust to reduce the number of non-urgent patient visits due to the ongoing pandemic, the researchers will endeavour to contact prospective participants either by telephone or email before their scheduled visit to the dermatology clinic to introduce them to the trial. Interested patients will be referred to a member of the study team who will explain the study. The patient will be informed about the terahertz imaging study and given the Patient Information Sheet. If they are happy to proceed, they will be consented for skinometry measurements by a Clinical Research Nurse or another qualified member of the team. Terahertz Skinometry imaging is undertaken on the day of the clinic visit.

## Terahertz imaging

After patient recruitment, individuals will be scanned with the THz skinometer. This will be performed by a delegate research team member in an appropriate environment as per the standard trust policy

A. Study arm 1: Participants will have a minimum of 6 quality readings of the THz Skinometer performed in the dry skin area, a control area if possible (similar site but without the skin condition) and a standard reference area (volar forearm with no skin condition present if possible). Participants will be asked to avoid their normal moisturisation routine in the hour prior to their scans. Then they will apply their emollient and wait 10 minutes to have another scan of

the control area and dry skin area. Finally, there will be another 10-minute wait before having the final scans of the control area and dry skin area. There will be a minimum of 6 quality scans in total for this group (if the volar forearm is used as the control area as well as the reference standard). Most likely there will be 7 scans in total (as the reference standard only needs to be measured once), however more scans may be required in order to identify the most suitable area to scan.

B. Study arms 2 and 3: A minimum of three quality readings of the THz skinometer ("scan") will be conducted after measuring the area of interest (AOI), a reference standard area (the volar forearm and an area of unaffected skin (control area measurement)). This will be the end of participation in the trial and the patient will continue the standard treatment pathway. Histological diagnosis will be collected remotely using patient notes/medical records at a later date (typically 2-4 weeks after biopsy) by a delegated research team member. No long-term clinical follow-up assessments will be performed as part of the SINATRA study.

Previous interventions:

The SINATRA study will collect preliminary pilot data from patient volunteers in a two-arm proof of concept study. One arm (group A) will consist of 50 patients with benign dry skin conditions (eczema, psoriasis, skin grafts, scars etc) and will compare the water content of skin before and after application of propriety emollients in common usage (e.g. E45®, Aveeno®, Doublebase® etc). This will add to the existing dataset that has been recorded from healthy non-patient volunteers. This may help to guide patient-specific emollient selection in the future. The second arm (group B) will consist of 100 patients with known or suspected skin cancer (incompletely excised basal cell carcinoma [BCC] with histologically proven radial margin involvement or pigmented lesions suspicious of malignant melanoma). Skinometry measurements will be taken in the clinic prior to planned skin surgery and later compared to the formal histology results after the primary (melanoma) or residual (BCC) tumour has been removed. This will add to the knowledge base to define the appearance of skin tumour under THz skinometry. The spectroscopic findings will not influence the established surgical management that will have been planned in conjunction with a Consultant Dermatologist or Plastic Surgeon and the patient.

The patient has a normal clinic visit and subsequent clinical investigations planned as required by the attending clinician. Considering the efforts in the Trust to reduce the number of non-urgent patient visits due to the ongoing pandemic, the researchers will endeavour to contact prospective participants either by telephone or email before their scheduled visit to the dermatology clinic to introduce them to the trial. Interested patients will be referred to a member of the study team who will explain the study. The patient will be informed about the terahertz imaging study and given the Patient Information Sheet. If they are happy to proceed, they will be consented for skinometry measurements by a Clinical Research Nurse or another qualified member of the team. Terahertz skinometry imaging is undertaken on the day of the clinic visit.

Terahertz imaging

After patient recruitment, individuals will be scanned with the THz skinometer. This will be performed by a delegate research team member in an appropriate environment as per standard trust policy

A. Study arm 1: A total of six readings of the THz skinometer ("scan") will be conducted after measuring the area of interest (AOI) and area of unaffected skin (control area measurement), at the following timepoints:

1. Pre-application THz skinometer ("scan") of the area of interest (AOI) and area of unaffected skin

2. Post-application scan I: the participant will then be requested to apply emollient, used regularly by them, following which after 10 minutes another THz skinometer ("scan") will be conducted of the area of interest and control area

3. Post-application scan II: a repeat scan of the area of interest and control area will be conducted 10 minutes following the post-application scan I.

This will be the end of participation in the trial and the patient will continue the standard treatment pathway.

B. Study arm 2: A total of two readings of the THz skinometer ("scan") will be conducted after measuring the area of interest (AOI) and an area of unaffected skin (control area measurement). This will be the end of participation in the trial and the patient will continue the standard treatment pathway.

Histological diagnosis will be collected remotely using patient notes/medical records at a later date (typically 2-4 weeks after biopsy) by a delegated research team member. No long-term clinical follow-up assessments will be performed as part of the SINATRA study.

## **Intervention Type**

Other

## **Primary outcome(s)**

The number of patients screened, eligible, recruited, withdrawn and retained during the study, recorded through screening activity at the end of the study

## **Key secondary outcome(s)**

Current secondary outcome measures as of 20/03/2023:

Objective difference in skin hydration between normal skin and dry skin conditions, benign pigmented skin lesions, skin containing residual basal cell carcinoma and skin containing malignant melanoma. For the dry skin arm, water content will be measured using THz skinometer scan data to observe the differences in pre- and post-emollient application. For cancer and benign pigmented skin lesion arms, skin hydration will be measured using THz skinometer scan data to investigate whether this may indicate the presence of residual basal cell carcinoma after primary excision, primary BCC or the localised inflammation caused by melanoma skin cancer compared to benign variants (seborrheic keratosis or other).

Previous secondary outcome measures:

Objective difference in skin hydration between normal skin, benign skin conditions, skin containing residual basal cell carcinoma and skin containing malignant melanoma, measured using THz skinometer scan data with formal reported histological analysis as part of the standard skin cancer management pathway, measured for arm A before histology is taken and for arm B before and after applying the chosen emollient.

## **Completion date**

15/03/2023

# **Eligibility**

## **Key inclusion criteria**

Current participant inclusion criteria as of 20/03/2023:

Study arm 1 (Benign dry skin condition) – patients, members of the public or NHS staff:

1. Aged 18 years and over
2. Diagnosed with dry skin conditions (e.g. eczema, psoriasis, scars etc.)
3. Capacity to give informed consent

Study arm 2 (Known or Suspected Skin Cancer) – patients only:

1. Aged 18 years and over
2. Patient to have ONE of the following TWO diagnoses:
  - 2.1. Confirmed or suspected basal cell carcinoma (BCC) skin cancer, for example: incompletely excised BCC with histologically proven radial margin involvement, OR biopsy-proven BCC (e.g., punch biopsy or incision biopsy); OR clinically diagnosed BCC
  - 2.2. Clinically suspicious pigmented skin lesion (suspected melanoma) with a plan for surgical biopsy
3. Capacity to give informed consent

Study arm 3 (Clinically Benign Pigmented Lesions) – patients only:

1. Aged 18 years and over
2. Diagnosed with a clinically non-suspicious pigmented skin lesion (seborrheic keratosis or other) referred by GP on a suspected skin cancer diagnostic pathway (2WW)
3. Capacity to give informed consent

Previous participant inclusion criteria:

Study arm 1 (dry skin condition):

1. Aged 18 years and over
2. Diagnosed with dry skin conditions (e.g. eczema, psoriasis, scars)
3. Capacity to give informed consent

Study arm 2 :

1. Aged 18 years and over
2. Confirmed or suspected skin cancer (incompletely excised BCC with histologically proven radial margin involvement, biopsy-proven BCC or pigmented lesions suspicious of malignant melanoma)
3. Diagnosed with an incompletely excised basal cell carcinoma skin cancer (either radial margin involvement on primary excision or following diagnostic punch biopsy).
4. Clinically suspicious pigmented skin lesion (suspected melanoma) with a plan for surgical biopsy
5. Capacity to give informed consent

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

## **Total final enrolment**

79

## **Key exclusion criteria**

Current participant exclusion criteria as of 20/03/2023:

Study Arm 1 (Benign dry skin condition) – patients, members of the public or NHS staff:

1. Previous allergy or sensitivity to propriety emollients in common usage (e.g. E45®, Aveeno®, Doublebase®etc.)
2. Area of interest is inaccessible to the THz skinometer for scanning

Study arm 2 (Known or suspected Skin Cancer) – patients only:

Area of interest is inaccessible to the THz skinometer for scanning

Study arm 3 (Clinically Benign Pigmented Lesions) – patients only:

Area of interest is inaccessible to the THz skinometer for scanning

Previous participant exclusion criteria:

Exclusion criteria (study arm 1, benign dry skin condition):

Previous allergy or sensitivity to propriety emollients in common usage (e.g. E45®, Aveeno®, Doublebase®)

## **Date of first enrolment**

15/03/2022

## **Date of final enrolment**

15/03/2023

## **Locations**

### **Countries of recruitment**

United Kingdom

England

### **Study participating centre**

**University Hospital Coventry & Warwickshire**

Clifford Bridge Road

Walsgrave

Coventry

United Kingdom

CV2 2DX

## **Sponsor information**

### **Organisation**

University Hospitals Coventry and Warwickshire NHS Trust

ROR

<https://ror.org/025n38288>

## Funder(s)

### Funder type

Charity

### Funder Name

Cancer Research UK; Grant Codes: C71817/A30093

### Alternative Name(s)

CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Other non-profit organizations

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the chief investigator, Prof. Joseph Hardwicke. (Joseph.hardwicke@uhcw.nhs.uk) by written application that will need to also be approved by the sponsor. Only anonymised data will be shared with external researchers. Consent from participants is being obtained to allow the researchers to share their data anonymously.

### IPD sharing plan summary

Available on request

### Study outputs

| Output type                     | Details  | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|--|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | In vivo Terahertz Sensing of Skin Cancer Patients          | 02/03/2025   | 29/04/2025 | Yes            | No              |
| <a href="#">Results article</a> | In vivo terahertz sensing of psoriasis and eczema patients | 30/07/2024   | 29/04/2025 | Yes            | No              |
| <a href="#">HRA research</a>    |  |              | 28/06      |                |                 |

[summary](#)

[Protocol file](#)

version 2.0

|                |                |    |    |
|----------------|----------------|----|----|
|                | /2023          | No | No |
| 08/04<br>/2022 | 28/06<br>/2022 | No | No |