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

Submission date
08/02/2022

Recruitment status
No longer recruiting

Registration date
11/02/2022

Overall study status
Completed

Last Edited
29/04/2025

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 (UK)

Contact information

Type(s)
Scientific

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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

ClinicalTrials.gov (NCT)
Nil known

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, skingrafts, 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, skingrafts, 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 (seborrhoeic 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
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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?
Results article	In vivo Terahertz Sensing of Skin Cancer Patients	02/03/2025	29/04/2025	Yes	No
Results article	In vivo terahertz sensing of psoriasis and eczema patients	30/07	29/04	Yes	No

		/2024	/2025		
HRA research summary			28/06/2023	No	No
Protocol file	version 2.0	08/04/2022	28/06/2022	No	No