

COSMOS

Characterisation Of Skin MicroStructure in normal and atrophied States

Research team: Dr Haleema Alfaiakawi, Dr Simon Danby, Dr Robert Byers, Kirsty Brown and Prof. Michael Cork.

Participant Information Sheet for Adults

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please feel free to discuss this information with your family, a healthcare professional or study team member.

Thank you for taking the time to read this document.

Summary

Why?	To find out how the microstructure of the skin differs in a diverse group of people with and without eczema.
What?	During a single visit, we will use non-invasive imaging and measurement devices to assess your skin at 7 anatomical locations (forehead, cheeks, upper arm, elbow crease, forearm, behind the knees and shin).
Where?	The Skin Barrier Facility on K-Floor of the Royal Hallamshire Hospital. We can arrange transport to and from the appointment for you.
Who?	We are looking for 150 people with no history of chronic skin conditions (except acne) and 30 people with eczema who have been using topical steroids. All ages are needed for both groups, starting from 6 months old.
When?	The single study visit will last up to 3 hours and can be arranged at a convenient time for you during normal working hours (Monday to Friday between 9am- 5pm).

What are we trying to find out?

We want to define the normal structural features of healthy skin in a diverse group and determine the effect of age, sex, and ethnicity. We then want to investigate how these features differ in people suffering from eczema who have used topical corticosteroids for long periods of time. This is a feasibility study, which means that we hope to use the results of this project to inform the design of a new, much larger study in the future.

Why have I been invited?

You are being invited to take part because you either have healthy skin (no history of chronic skin conditions other than acne) or you have suffered from eczema (also known as atopic dermatitis) and have been using topical corticosteroids regularly for more than 3 months.

Do I have to take part?

No. It is up to you whether you would like to take part. Consider the information in this sheet to help you decide, and feel free to contact us if you have any questions. If you do decide to take part you are free to withdraw at any time, without giving a reason - just let a member of the study team know of your wish to withdraw (see contact details below).

What will happen if I take part?



Pre-screening phone call

 10 minutes

If you would like to take part, the first step is a pre-screening phone call, which can be arranged at a convenient time for you, within normal working hours (we can also do this in person at our test centre if you prefer). During this call, we'll provide an overview of the study and ask you a couple of questions to determine whether it is likely that you are eligible. If it appears that you meet the basic eligibility criteria, we will arrange an appointment for you to visit us. We can arrange taxis to and from the hospital.



Preparation

During the 24-hour period before your appointment, you should not apply any topical products (including make-up and moisturisers) directly onto the skin of your forehead, cheeks, upper arms, elbow creases, forearms, behind your knees or your shins. If you have eczema, we will ask you to refrain from using any treatments for at least 6 hours before the visit. Please discuss this with the study investigator if you believe this duration may be challenging.

Study visit at the Royal Hallamshire Hospital

 2-3 hours in total



At the beginning of the visit, there will be an opportunity for you to ask any questions you may have. You will then be asked to sign a consent form, of which you will be given a copy. We will then ask you a series of questions about your health and any medicines you may take in order to confirm your suitability for the study. Not everyone will be eligible to take part. We would also like to look at the effect of stress on skin by asking you to complete a short questionnaire about how you've been feeling in the last few weeks.



The skin sites we are interested in are your forehead, cheeks, upper arms, elbow creases, forearms, behind your knees and your shins. We will ask you to acclimatise the skin at these places to room conditions for 20 minutes. Please wear appropriate clothing for this (i.e., short sleeves) and consider bringing a pair of shorts to change into. We may need to discreetly mark out the measurement sites (except those on the face) using a marker pen which is easily removed by washing at the end of the study. Excess hair can interfere with the measurements, so with your permission, we may need to trim this if it will affect image quality.



We will make a visual assessment of the condition of the skin at each area and then collect some images and measurements from those areas (see below "What assessments will we do?").

Saliva sample collection*



First thing in the morning after your visit you will need to collect 2 saliva samples from yourself. These samples will be used to analyse your cortisol levels. Cortisol is a stress hormone, the levels of which are linked to your mood and could affect skin structure. One sample should be collected immediately when you first wake and another exactly 30 minutes later. We will provide full instructions and all the equipment required. The procedure is straightforward, and you can call us anytime if you have any questions about it. We will contact you by phone call or text the day before you're required to collect the samples to remind you.

**This is optional. You don't have to provide saliva samples if you do not wish to.*

What assessments will we do?

1. **Digital photographs.** We will use a digital camera to take pictures of your skin at the assessment sites. These will be used for our internal reference when looking back at the data. While these images are quite zoomed-out, we will be careful not to capture your eyes or whole face in the images. You will be able to check each of the photos we collect to confirm that you are happy with them.

2. **Trans-Epidermal Water Loss (TEWL).** This probe measures how quickly you lose water through your skin. Each measurement takes around 2 minutes.
3. **Optical Coherence Tomography (OCT).** For this, we will hold a probe gently against your skin for 2-3 minutes per image. This device shines a beam of harmless light into the skin and creates an image showing the skin layers and blood vessels.
4. **Polarisation Sensitive Optical Coherence Tomography (PS-OCT).** This works in the same way as OCT, but this machine looks at how the collagen fibres in your skin are organised.

Having an OCT image taken is harmless and only takes a couple of minutes



What are the possible benefits of taking part?

There are no direct benefits to you for taking part in this study. However, by taking part you will help us to better understand eczema, a condition that affects skin microstructure. For attending the study visit you will be given a £20 voucher to say thank you for the time you have given up (this is normally an Amazon voucher, but we can issue Love2Shop vouchers upon request). An additional £10 voucher will be provided upon return of the saliva sample.

What are the possible disadvantages and risks of taking part?

All the techniques used are completely harmless and simply involve shining light into or resting on the skin, so we do not envisage any disadvantages or risks as a result of taking part.

Who is responsible for my personal information?

The Sheffield Teaching Hospitals (STH) NHS trust is the sponsor for this study based in the United Kingdom. We will be using information from you to undertake this study and will act as the data controller. This means that we are responsible for looking after your information and using it properly. We will keep identifiable information about you for up to 5 years after the study has finished.

How will we use information about you?

We will need to use information from you, and from your medical records, for this research project. This information will include your initials, name, and contact details. 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.

If you provide your consent, The University of Sheffield will hold your contact details for up to 5 years after the end of the study so that they can send you information about other skin research opportunities with the Sheffield Dermatology Research group. This will be done by email; however, information can be sent out by post if preferred. If at any time you no longer wish to receive this information you can withdraw by email (skinresearch@sheffield.ac.uk) or by contacting the study team. You do not need to provide a reason.

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.
- 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 sending an email to sth.infogov@nhs.net, or
- by ringing us on 0114 2265151.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be kept strictly confidential. Any information about you that leaves the site will have your name and any personal identifiable details about you deleted, so that you cannot be recognised by it. This includes data that are transmitted electronically. Each participant will be allocated a unique study number, which will be used for recording demographic and study data. All electronic data will be stored on a secure server, managed by the University of Sheffield, and will be identifiable only by the unique study number. Personal contact details will be recorded separately. Any information included in written reports/presentations will not identify you by name. Only the members of the research team will have access to your personal identifiable data.

What is the legal basis for processing my personal data?

According to data protection legislation, we are required to inform you that the legal basis we are applying in order to process your personal data is that 'processing is necessary for the performance of a task carried out in the public interest' (Article 6(1)(e)). Further information can be found in the University's Privacy Notice (<https://www.sheffield.ac.uk/govern/data-protection/privacy/general>) and in the EU Regulation (EU) 2016/679. As we will be collecting some data that is defined in the legislation as more sensitive (information about your ethnicity and health), we also need to let you know that we are applying the following condition in law: that the

use of your data is 'necessary for scientific or historical research purposes'. In accordance with The General Data Protection Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, the data will not identify any persons taking part in the study.

What will happen to any samples I give?

Your samples will be treated as a gift. They will be kept in a secure location within The University of Sheffield Medical School. Access to your samples, which will not be labelled with personal identifiable information, will be restricted to authorised designees only. Your samples will be used to measure your cortisol levels only and will be disposed of by the end of this study. We will not share your personal identifiable information with this or any other organisation. Should you choose to withdraw from the study we will destroy your samples upon request.

What will happen to the results of the research study?

We may use information from the study to write scientific reports, presentations, and marketing information but they will not include any information that makes it possible for you to be identified. We will distribute a summary of our findings to all participants at the close of the study by email using the address you provide.

Anonymised study information may be used to support other research in the future and may be shared with other organisations. We will ask for your explicit consent for your data to be shared in this way.

Who is organising and funding this research?

This study is organised and funded by researchers at The University of Sheffield and Sheffield Teaching Hospitals NHS Foundation Trust.

Who has ethically reviewed the project?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, dignity, and wellbeing. This study has been reviewed and given a favourable opinion by the Yorkshire & The Humber Sheffield Research Ethics Committee (Ref: 24/YH/0103) and the Sheffield Teaching Hospitals NHS Trust (Ref: STH 23036).

What if there is a problem?

If you have a concern about any aspect of this study, you should speak to a member of the research team who will do their best to answer your questions (Tel: 0114 215 9539, Email: skinresearch@sheffield.ac.uk). If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Services Team (The Royal Hallamshire Hospital, Glossop Road, Sheffield, S10 2JF; telephone 0114 271 2400).

In the event that something goes wrong, and you are harmed during the research due to someone's negligence then you may have grounds for legal action and compensation, but you

may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

How do I get to the Skin Barrier Facility?

The Skin Barrier Facility is located within the Royal Hallamshire Hospital, Glossop Rd, Sheffield, S10 2JF. You will find us on K-Floor of the main tower building. The best way to reach us is to enter the hospital from the main entrance on B-Road and take the lifts in the lobby directly ahead up to K-floor. Go through the double doors in the lift lobby, turn right and use the phone on the wall to call the office on 59539 and we'll come and let you in. For more details on how to find the Royal Hallamshire Hospital please go to the Royal Hallamshire Hospital website (<https://www.sth.nhs.uk/our-hospitals/royal-hallamshire-hospital>) where you can also find details for public transport and parking (if you don't want us to arrange a complimentary taxi for you) as well as a site map.

What next?

If you would like to take part or discuss anything in this information sheet, please contact:

COSMOS Research contact: Haleema, Abi & Kirsty

Contact Number: 0114 215 9539

Contact Email: skinresearch@sheffield.ac.uk

The study team can be contacted at: Division of Clinical Medicine, The University of Sheffield Medical School, Beech Hill Road, Sheffield, S10 2RX.



0114 2159539



skinresearch@sheffield.ac.uk



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Thank you for reading this
Please ask any questions if you need to