Sheffield Teaching Hospitals NHS
NHS Foundation Trust

University of Sheffield | Sheffield Dermatology Research

Skin bioMARkers for atopic eczema Therapy evaluation: Patient Information Sheet and Informed Consent Form

Study Title	Validation of a novel composite of skin biomarkers as a primary outcome measure for evaluating the safety of treatments for atopic dermatitis: a randomized controlled trial (phase 2) comparing the effects of crisaborole 2% ointment to betamethasone valerate 0.1% cream on skin structure and function in participants with atopic dermatitis.
Acronym	SMART
Date and Version	PIS V4_28 Jan 2021 ICF V1_30 Oct 2019
IRAS#	269415
NCT#	NCT04194814
EudraCT#	2019-002643-23
Chief Investigator	Prof Michael J. Cork, Consultant Dermatologist & Head of Academic Dermatology Sheffield Dermatology Research
Co-Investigators	Dr Simon Danby, Research Fellow (Trial Manager) Prof Stephen Matcher, Professor of Biophotonics, Miss Rosie Taylor, Principal Consultant, Dr Rob Byers, Research Associate
Governance Sponsor	Sheffield Teaching Hospitals (STH) NHS Trust
Sponsor Reference	STH19966
Research Ethics Committee (REC)	East Midlands - Derby Research Ethics Committee
REC Reference	20/EM/0006
Funder	Pfizer, Inc.
Funder Reference	WI242083-UK-University of Sheffield-Eucrisa

Sheffield Dermatology Research

The University Of Sheffield.

SMART

Skin bioMARkers for atopic eczema Therapy evaluation (SMART)

Participant Information Sheet

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 conducted and what it would involve for you. Please feel free to discuss this information with your family, a healthcare professional or a study team member. Thank you for taking the time to read this document.

SUMMARY

Why? To see the changes within the skin brought about by different topical anti-inflammatory treatments for eczema. To do this, the effects of the corticosteroid betamethasone valerate will be compared to the non-steroidal crisaborole. It will reveal whether crisaborole treatment causes the skin thinning previously reported for corticosteroid treatment of the skin. This will also help develop new ways to evaluate and compare the effects of topical treatments in future clinical trials.

What? Using non-invasive imaging technology combined with other non-invasive skin tests we will assess the properties of the skin on your forearms before, during and after treatment of the skin with the two topical treatments for eczema for 4 weeks (twice daily application). The treatments include the commonly prescribed corticosteroid betamethasone valerate cream (marketed as Betnovate cream in the UK) and the new non-steroidal crisaborole ointment (currently marketed in the US as Eucrisa, and pending marketing authorisation in the UK).

Who? We are looking for 37 volunteers aged 18-65 years old with eczema

Where? The [insert site specific location as agreed with study sponsor] of the Royal Hallamshire Hospital. We will arrange taxi transfers to and from the appointment for you.

When? Participation takes place over 2 months, during which time there are 4 visits to the test centre for skin assessments and another 5 for treatment checks. The skin assessment visits last about 2-3 hours (treatment checks last about 20 min) and can be arranged at a convenient time for you during normal working hours (Monday – Friday).

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the study.

PART 1

What are we trying to find out?

The first-choice drug treatment for mild-moderate eczema is currently a topical corticosteroid, like Betamethasone valerate cream. By topical, we mean the treatment is intended for application directly to the skin. Whilst topical corticosteroids are effective at treating eczema, they have been found to cause unwanted skin changes, such as skin thinning, if used inappropriately over long periods of time. Exactly how much unwarranted thinning is caused by different treatment routines is unclear, so we want to identify some skin bio-markers of skin thinning. We are specifically looking for early skin damage signals that may appear ***before*** adverse effects can be observed in the clinic. This will be done by using non-invasive skin imaging techniques that are similar to ultrasound.

Topical crisaborole ointment is a new non-steroidal drug treatment for eczema that appears to be as effective as some topical corticosteroids, and is not expected to cause abnormal skin thinning. A comparison between crisaborole and a topical corticosteroid is therefore a good way to find important skin markers. Betamethasone valerate cream is one of the most commonly prescribed topical corticosteroids for eczema in the UK. Both crisaborole and betamethasone valerate have already been tested in clinical trials for clinical efficacy, and so efficacy will not be assessed again here. This study will confirm whether or not crisaborole causes the same unwarranted skin thinning caused by betamethasone valerate in a direct comparison of the two treatments. Having a better understanding of the unwanted effects of these treatments will be informative for prescribers/doctors and patients.

Why have I been invited?

You are being invited to take part because you are over the age of 18 years and have recently suffered from eczema (also known as dermatitis). By this we mean that you have experienced symptoms or displayed signs of this itchy skin condition within the past 12 months. You do not need to have visible signs of eczema at the moment.

We are specifically looking for people who are 'clear' or 'almost clear' of the signs of eczema on their forearms based on an assessment by the study investigator (signs of eczema in the areas around the forearm, including the elbow flexure are fine). Assessing this is prone to different interpretations, so if you would like to take part please feel free to get in touch and the study investigator will be happy to make the assessment.

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.

What will happen if I take part?

An overview of the study is presented in the flow-diagram below, with further detail provided below.

Pre-screening phone call (approx. 5-10 min): The first step will be to arrange a phone call with you so that we can determine how likely it is that you are eligible to take part in the study. We'll do this by asking you a couple of questions, including questions about your skin health. If it looks like you may be eligible we will arrange for someone from the study team to contact you to book your screening and consent visit at a convenient time for you. You will be offered a complimentary taxi to and from the test site. Please note that we cannot fully assess your eligibility to take part over the phone, and so cannot guarantee you a place on the study.

Screening & Consent Visit (approx. 30-60 min): A member of the study team will provide an overview of the study and answer any questions you may have. You will then be asked to sign a consent form, and you will be given a copy of the form to keep. Then we'll determine whether you meet the criteria to take part in this study by:

- Asking you a series of questions, including questions about your health and any medicines you may take.
- Performing a physical examination of your skin to grade the severity of your eczema overall. The dermatologist will need to see the signs of eczema on your body to assess its severity.
- Asking female participants to take a pregnancy test and undertake a reliable form of contraception for the duration of the study (further details below).

If you are eligible to take part the study team will then arrange your study visits with you. We will also notify your GP of your involvement in the study; this is standard practice for a clinical study like this.

Wash-out: Some participants, who are currently using treatments for eczema, will need to undergo a 'wash out' period, where the use of these treatments is stopped, prior to the first study visit. The duration of the wash-out depends on the type of treatment, and varies from 7 days for emollients to 12 weeks for intravenous biologic therapies.

We appreciate that this may be challenging for patients with more severe eczema and ask that you discuss your topical treatment needs with a member of the study team prior to your visit. You can wash your skin as normal.

Visit 1, Day 1 (approx. 2.5-3 hours): If you've undergone a wash-out period we'll need to reconfirm eligibility at the start of this visit (approx. 30 min).

The skin sites we are interested in are your forearms. At each visit we will ask you to acclimatize the skin on your forearms to the room conditions for 20 minutes. Please wear appropriate clothing for this (i.e. short sleeves). We will need to mark out several measurement sites on each of your arms using a marker pen (as discreetly as possible). The marker is easily removed by washing the skin at the end of the study visit. Hair does interfere with the measurements, so if you have hair on your arms we may need to trim it.

Once acclimatised we will assess the condition of your skin in a number of ways, all of which are non-invasive (see "what procedures will we do?" below for further information). We will then collect a mouth swab sample and provide you with the two study treatments (Betamethasone valerate cream and Crisaborole ointment) and a treatment diary to record your usage. You'll need to apply both the treatments to different areas on your right and left forearms **twice daily for 4 weeks**. The skin site allocation (right/left) will be random.

Whilst taking part in the study, participants should consult with the study team before using any other medications.

Visits 2-5 and 6a, Days 1 to 12 and day 22 ± 3 days (approx. 20 min each): We need to monitor your treatment usage on 4 occasions during the first 2 weeks. This means attending the test centre so that we can weigh your treatments, review your treatment diary and observe you making a skin application. The scheduling of these visits is flexible during the first 12 days of treatment.

So that we can observe you applying the treatments we will send you reminders by text message (or telephone call if you prefer) to not apply the study treatments in the morning before visits 2-7.

Visit 6, Day 15 +/- 3 days (approx. 2.5 hours): At this visit we will repeat the same procedures as in visit 1, except we will not need to collect another mouth swab sample.

Visit 7, Day 29 +/- 3 days (approx. 3 hours): At this visit we will repeat the same procedures as in visit 6 and additionally collect a sample of your dead skin cells by using

adhesive discs (like Sellotape) in a process called tape-stripping (see "what samples will we collect?" for further information). Treatment stops at this point, so you'll need to return your diary and used treatments.

Visit 8, Day 57 +/- 4 days (approx. 2.5 hours): At this visit we will repeat the same procedures as in visit 6.

Pregnancy testing and contraception checks for female participants

There is no evidence to suggest that crisaborole ointment cannot be used during pregnancy. However, since this drug is new and its use has not yet been tested in pregnant women, we are taking the precautionary measure of ensuring participants are not pregnant and do not become pregnant during the study. This means female participants will be required to undertake a urine pregnancy test before, during and after the study. The test kit will be provided. In addition, all fertile female participants who are sexually active and at risk for pregnancy must agree to use a highly effective method of contraception consistently and correctly for the screening period, the duration of the active treatment period and for at least 28 days after the last dose of study treatment. The study investigator will discuss the options for contraception with participants as appropriate during the screening visit.

What procedures will we do?

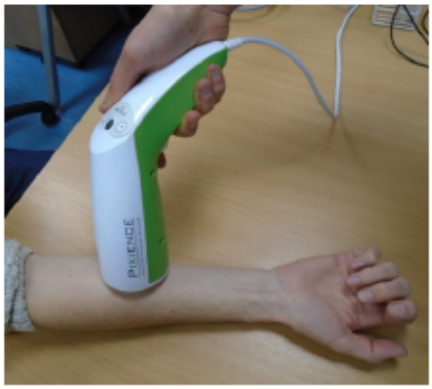
We will collect information in several ways, using a range of non-invasive techniques...

Visual assessment

This will involve looking at the condition of your skin by eye, if your skin has signs of eczema this will involve grading how severe the lesion(s) appear to be. We will perform both a local (just at the testing sites) and whole-body assessment of the extent and severity of eczema. For the whole-body assessment, the dermatologist will need to see the signs of eczema on your body to assess its severity.

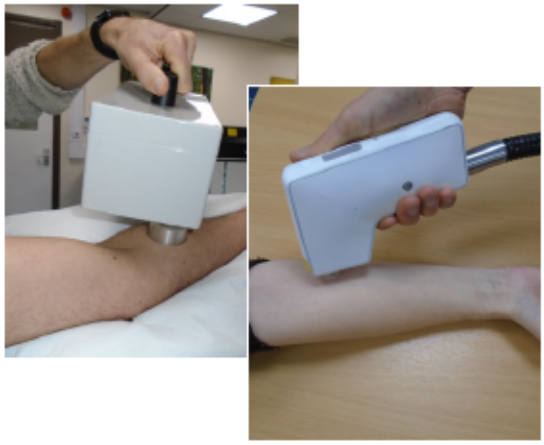
2D photographs

This involves placing a handheld camera probe gently against your skin at the imaging sites for a few seconds. This technique captures 'photographs' of your skin using a high-definition camera and controlled LED lighting. Because the photographs are taken of small areas of skin close-up you will not be identifiable from them, and you can review all of the photographs we collect. The photgraphs will be stored using a participant number and not your name.



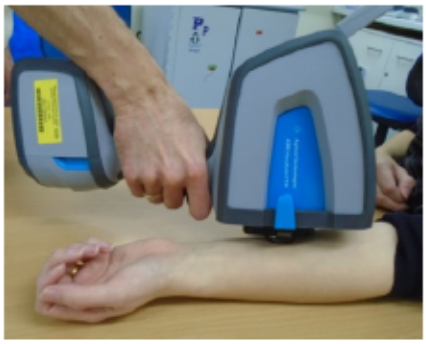
Optical Coherence Tomography (OCT)

This involves placing a handheld probe gently against your skin at the imaging sites for 2-3 minutes. This technique uses near infrared light, like that found in television remotes, to scan just beneath the surface of your skin. We will use two different types of OCT machine. With the first we can see the structure of the skin, including the shape of blood vessels. The second is used to see the connective fibres (collagen) in your skin.



FTIR spectroscopy

This will involve placing the device briefly in contact with your forearm. This device also uses infrared light and collects information on your skin composition.

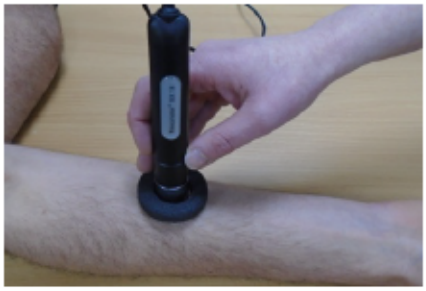


Transepidermal water loss (TEWL)

This will involve placing a probe on your skin for approximately 60 seconds. The probe measures how quickly water is lost through your skin, which indicates how well it is functioning as a barrier to water and allergens.

Skin redness

We will use a probe called the Mexameter to measure skin redness, this simply involves placing (touching) the probe against the surface of the skin for a few seconds. The measurment does not cause any redness. Measurements taken at baseline (visit 1) provide a reference point of how red your skin normally is. All subsequent measurements are compared to this reference.



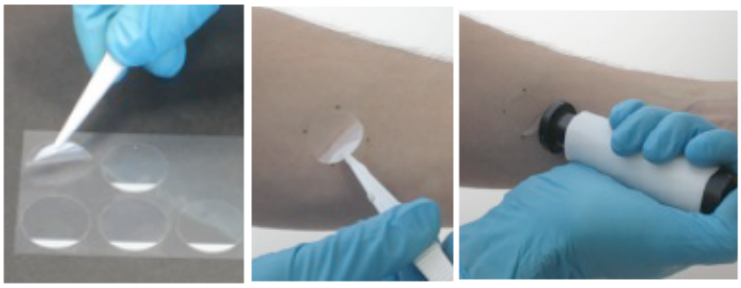
What samples will we collect?

We will collect the following tissue samples:

Mouth swab

We will collect a sample of your saliva using a buccal swab on your inner cheek so that we can obtain your DNA. By analyzing a part of your DNA we can determine whether you carry any of the genetic risk factors currently linked to an increased risk of eczema. We want to determine whether carriage of these markers affects your response to the treatments, and therefore whether genetic screening could help inform treatment choices. Please note that we will not be able to share your individual results of the genetic screening with you because it is currently unclear what the results mean. This is because the causes of eczema are complex, and while some genetic changes appear to increase risk, many people without eczema carry them too.

Tape-strip samples



This will involve collecting surface skin samples from your forearms using small sticky-tape discs to collect only the very top layers of skin cells, which are already dead and about to be shed naturally by the body. The sensation is equivalent to the sticking and removal of sellotape from the skin. A special spring-loaded plunger is used to apply the sticky discs with a consistent amount of pressure. We will analyse the discs in the laboratory to look at the composition of your skin.

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 find new ways of evaluating the effects of topical treatments on the skin, which could lead to the identification and development of safer topical treatments and treatment regimens.

Expenses and remuneration

For undertaking this study, you will be given £250 by direct bank transfer for your time, and to cover any expenses you may have incurred. If you do not want to provide your bank details we can provide Amazon Gift Vouchers instead. The £250 would need to be declared for tax and benefits purposes. This is in addition to the taxi transfers to and from the hospital, which we will arrange and pay for.

Are there any risks?

We do not anticipate any risks associated with the skin procedures, which are all non-invasive. Any skin reddening that occurs after tape-stripping is expected to dissipate in a few days. The study treatments are investigational medicinal products, and the risks associated with their use in this study are comparable to the risks of standard care for eczema. Treatment specific side effects are detailed in the next section.

Sometimes people have allergic reactions to ingredients that are in topical products. If you have any known allergies or sensitivities to common topical products (including cleansers), toiletries or their components, or adhesives, you should not take part in this study. It is very important to tell the investigator immediately if you have any known allergies or if you begin to have an allergic reaction. Some things that happen during an allergic reaction include a rash over the whole body; shortness of breath; wheezing; sudden drop in blood pressure; swelling around the mouth, throat, or eyes; fast pulse; or sweating. If you experience any of these side effects, contact your doctor or NHS direct immediately.

What are the study treatments?

The study treatments are both 'topical' products, intended to be applied directly onto the skin. All participants will receive both treatments to use at the same time on separate areas of skin on their forearms. There are no other study treatments. At the end of the study the treatments must be returned, and will not therefore be available to you for continued use.

Betamethasone valerate cream

Betamethasone valerate cream is currently marketed in the UK as Betnovate cream by Glaxo Wellcome UK Ltd. Every gram of cream contains 0.001 grams of the active ingredient, betamethasone (0.1% w/w) as valerate. It is widely prescribed by healthcare professionals for the treatment of eczema in short courses of no more than 4 weeks duration. We are conducting this study because the long-term inappropriate use of betamethasone valerate can cause unwarranted skin effects including skin thinning (atrophy). This is related to a lowering in the level of the hormone cortisol in the blood. Due to the short-duration of treatment involved in this study we do not expect any irreversible skin thinning to occur, and we'll be monitoring skin thickness closely throughout the study for your safety.

Like all medicines, betamethasone valerate can cause side effects, although not everybody gets them.

- Very common side effects (these may affect 1 in 10 people or more, or ≥10%): none;
- Common side effects (these may affect up to 1 in 10 people, or up to 10%): a feeling of burning, pain, irritation or itching where the cream is applied.
- Very rare side effects (these may affect up to 1 in 10,000 people, or up to 0.01%): an increased risk of infection; an allergic skin reaction where the cream is applied; rash, itchy bumpy skin or redness of the skin; thinning and dryness of your skin and it may also damage or wrinkle more easily; stretch marks may develop; blood vessels under the surface of your skin may become more noticeable; an increase or reduction in hair growth

or hair loss and changes in skin colour; weight gain, rounding of the face; delayed weight gain or slowing of growth in children; bones can become thin, weak and break easily; cloudy lens in the eye (glaucoma); a decreased level of the hormone cortisol in your blood; increased blood sugar levels or sugar in the urine; high blood pressure.

- Not Known (frequency cannot be estimated from the data available): blurred vision.
- EFFECTS ON PREGNANCY AND LACTATION: There is limited information from the use of betamethasone valerate in pregnant and breastfeeding women. As a precaution, women who are pregnant or intending to become pregnant and breastfeeding women will not be included in this study.

For further information on topical corticosteroids you can visit the National Eczema Society webpage http://www.eczema.org/corticosteroids

Crisaborole ointment

Crisaborole ointment is a new anti-inflammatory treatment for eczema. Every gram of ointment contains 0.02 grams of the active ingredient crisaborole (2%). Crisaborole is a phosphodiesterase 4 (PDE4) inhibitor indicated for the treatment of mild to moderate atopic eczema. Crisaborole ointment is not currently marketed in the UK, however it is currently marketed in the United States and Canada under the brand name Eucrisa, and was most recently approved for marketing in Australia and Israel. It is the intention of Pfizer to bring crisaborole to the UK pending local regulatory approval.

Like all medicines, crisaborole can cause side effects, although not everybody gets them.

- Very common side effects (these may affect 1 in 10 people or more, or ≥10%): none;
- Common side effects (these may affect up to 1 in 10 people, or up to 10%): pain at the area of applied study medication;
- Uncommon side effects (these may affect up to 1 in 100 people, or up to 1%): worsening atopic dermatitis or eczema, itching at the area of applied study medication;
- Rare side effects (these may affect up to 1 in 1,000 people, or up to 0.1%): none;
- Other types of application site skin reactions observed in previous clinical studies have included: redness (erythema); irritation; itching (pruritus); infected or inflamed hair follicles (folliculitis); redness, skin bumps, burning, stinging, swelling, itching, oozing and/or crusting of the skin (dermatitis); and pain.
- EFFECTS ON PREGNANCY AND LACTATION: In animal studies, crisaborole ointment 2% did not have effects on fertility (the ability to become pregnant or maintain pregnancy), birth defects or delivery events (delayed birth, stillborn births or sudden newborn death). Clinical studies of pregnant and breastfeeding women have not been performed for crisaborole ointment 2%. Women who are pregnant or intending to become pregnant and breastfeeding women will not be included in clinical studies.

For further information on Eucrisa you can visit https://www.eucrisa.com/

This completes Part 1

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

What if relevant new information becomes available?

Sometimes we get new information about the treatment being studied. If this happens, someone from the research team will tell you and discuss whether you should continue in the study.

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 in order to undertake this study and will act as the data controller for this study. 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 15 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, NHS number, 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. Some of your information will be sent to Pfizer (the Funder), based in the United States of America. They must follow our rules about keeping your information safe.

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.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop, unless we are not able to do this for your safety. We will discuss this with you in detail if this situation occurs.
- 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/data that leaves the hospital will have your name and address deleted, including data 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. Access to your medical records held by Sheffield Teaching Hospitals NHS Foundation Trust is required to assess your medical history, where available, and to document your involvement in a clinical trial. Where participants are not currently undergoing treatment at Sheffield Teaching Hospitals NHS Foundation Trust, a new set of medical notes will be created. Study data, including the study images, will not ordinarily be stored in the medical notes, unless pertinent to the follow-up of an adverse event occurring during your involvement in the study. Personal contact details will be recorded separately, accessible only to the direct study team. Any information included in written reports/presentations will not identify you.

What will happen to any samples I give?

Your samples will be treated as a gift. All samples collected will be labeled only with your unique study code, initials and date of collection; they will be kept in a secure location within The University of Sheffield Medical School/Royal Hallamshire Hospital. Access to your samples will be restricted to members of our research team only. All saliva samples will be destroyed at the end of the study. With your permission, extracted DNA samples and superficial skin samples (tape-strips) will be kept for a maximum of 10 years under the custodianship of the

Principal Investigator. It is likely that these samples will be used to support future studies, this may include studies undertaken by the funder, Pfizer. Pfizer would only receive anonymized samples and appropriate research ethics committee approval will be sought. Should you choose to withdraw from the study we will destroy your sample upon request.

What will happen to the results of the research study?

We will use the information from this study to write scientific reports and publications, but they will not include any information which 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.

Who is organising and funding this research?

This study is organised by researchers at The University of Sheffield and Sheffield Teaching Hospitals NHS Foundation Trust. The study is funded by Pfizer, who manufacture crisaborole ointment. Employees at Pfizer have reviewed the study for quality and will be updated on the progress of the study throughout, however as an investigator-led study Pfizer will have no direct involvement in the conduct of the study. At the end of the study the results will be shared with Pfizer in a fully anonymised form.

The full study title for reference is "Validation of a novel composite of skin biomarkers as a primary outcome measure for evaluating the safety of treatments for atopic dermatitis study 1: a randomized controlled trial (phase 3) comparing the effects of crisaborole ointment to betamethasone valerate cream on skin structure and function in atopic dermatitis patients".

Who has reviewed this study?

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 XXXXXXXXXXXXX Research Ethics Committee (Ref: XX/XX/XXXX) and the Sheffield Teaching Hospitals NHS Trust (Ref: STH 19966).

What if there is a problem?

If you have a concern about any aspect of this study, you should speak to researchers who will do their best to answer your questions (Tel: XXXXXXXXXX). 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 2712400).

In the event that something goes wrong and you are harmed during the research 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 to find us?

The [insert site specific location as agreed with study sponsor] is situated [insert site specific location] in the Royal Hallamshire Hospital, a mile from the city on the Sheffield Teaching Hospitals Trust's central campus. [insert site specific location directions]. 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 complementary taxi for you) as well as a site map.

What next?

If you would like to take part please contact:

SMART Researcher: ----------

Contact Number: XXXX XXXXXXX

Contact email: XXXX@sheffield.ac.uk

To know more about the study or discuss anything in this information sheet then please contact the study team: Department of Infection, Immunity and Cardiovascular Disease, The University of Sheffield Medical School, Beech Hill Road, Sheffield, S10 2RX.

 **0114 2159539**  **skinresearch@sheffield.ac.uk**  **@Shef_Derm**

 **Sheffielddermatologyresearch**  **www.shef.ac.uk/iicd/dermatology**

Thank you for reading this

Please ask any questions if you need to

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Sheffield Dermatology Research

The University Of Sheffield.

SMART

Skin bioMARkers for atopic eczema Therapy evaluation

Principal Investigator: Michael Cork

Informed Consent Form

Participant Screening Number: _____

		Please initial box:
1.	I confirm that I have read and understood the information sheet dated 28th Jan 2021 (version 4) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason, and without my medical care or legal rights being affected.	☐
3.	I understand that relevant parts of my study and/or medical records collected during my involvement in the study, may be looked at by individuals from the study Sponsor, Sheffield Teaching Hospitals NHS Trust, from regulatory authorities or from third party contract research organisations (an organisation that is contracted to perform all or some trial related tasks on behalf of the sponsor, such as monitoring the quality and safety of a trial or analysing sets of trial data). I give permission for these individuals to have access to my study records.	☐
4.	I understand that the anonymised information collected about me, and held by the University of Sheffield, may be used to support other research in the future, and may be shared with other organisations, including for example the study Funder, Pfizer. Anonymised information is study data that has had your personal identifiable information, such as your name, initials and date of birth, removed.	☐
5.	I agree to my General Practitioner being informed of my participation in the study. This is standard practice for any clinical study.	☐
6.	I understand that I will be required to supply a sample of my saliva so that my DNA can be obtained and analysed for common genetic risk factors linked to eczema.	☐

7.	[Optional] I give my permission for my DNA to be kept after the end of this study in fully anonymised form (meaning that nobody will be able to identify the sample as mine) for upto 10 years so that it can be used in future research.	☐ Yes ☐ No	☐
8.	[Optional] I give my permission for my 'tape-strip' skin samples to be kept after the end of this study in fully anonymised form (meaning that nobody will be able to identify the sample as mine) for upto 10 years so that it can be used in future research.	☐ Yes ☐ No	☐
9.	[Optional] I am happy to be contacted by the research team about other research studies being conducted by the Sheffield Dermatology Research group within the next 5 years. I understand that I may opt out of any future contact at any point by informing the research team.	☐ Yes ☐ No	☐
10.	I agree to take part in the above study.		☐

Name of participant	Date	Signature
Name of person taking consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes.