Rapid Eczema Trials
Creating research together

Participant Information Sheet

Version 1.2_14-Jan-2026
IRAS Project ID: 329123

Keep Control of Eczema Study – how to treat eczema flare-ups

Have you ever wondered how long to use your steroid creams for when you have a flare-up of eczema?

If so, this study is for you!

What is an eczema flare-up?

An eczema flare-up is when the **skin becomes more itchy or sore than usual.**

Flare-ups are usually treated with steroid creams or ointments.

When treating eczema flare-ups, it is not always clear how long you should treat eczema for. Some people find it hard to know when to stop using their steroid creams.

We are looking for people to take part in a study.

Study Summary

The study will test if it is helpful to give specific advice about how long to treat flare-ups for. Treating for slightly longer could help keep eczema controlled for longer.

When we say "you" in the information below, this means the person taking part in the study – that could be yourself or your child, or someone that you look after.

What does taking part involve?

If you agree to take part in the study, we will put you into one of two groups:

- **Specific advice**: people in this group will be given advice to treat their eczema flare-ups for slightly longer.

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- **Treat as usual**: people in this group will be given advice to treat their eczema as usual.

You will not be able to choose which group you are in, this will be done randomly to make sure our study is a fair test.

- You will be in the study for **4 months**
- You will be given advice about how to treat your eczema flare-ups
- You will be asked to **answer questions online** about your eczema **each week for 16 weeks**
- You can **continue to use your usual eczema treatments**

Who can take part?

We are looking for **adults and children** (aged 1 year or older) who **already use steroid creams** to manage their eczema. When we say steroid creams, we mean both steroid creams and steroid ointments.

If you are not sure whether your eczema flare-up cream is a steroid cream or not, you can check **here** or contact the study team (details below).

We ask that you do not start any new eczema treatments during the study, if possible.

Before signing up, you will be asked a few simple questions to see if this study is right for you.

I am interested in taking part in the study! What do I do now?

Please read the information below and/or watch our videos to help you decide if taking part is right for you or your child.

If you would like to take part, click the 'Join now' button on our website: https://rapideczematrials.org/keep-control-study/

Contact details for the study team - please get in touch if you have any questions: RapidEczemaTrials@nottingham.ac.uk

Why is this study important?

- People with eczema have chosen this question as it is something that they want to know the answer to.
- Many people are given different advice about how long to use their steroid creams for. This can be confusing and frustrating for people living with eczema.
- Sometimes eczema can still be under the skin, even when the skin looks OK. If the eczema isn't treated completely, it may come back more quickly.

- This study will help answer important questions about the best way for people with eczema to treat eczema flare-ups. By taking part in this study, you will be helping many more people to understand how to take better care of their eczema.

If you would like to help find out how long to use steroid creams during an eczema flare-up, please join our study.

Things to know before joining the study

1. Who can take part?

You **can** take part if you:

- Have eczema
- Live in the UK
- Are at least 1 year old in age
- Are willing to use your usual steroid creams for slightly longer than usual when you have an eczema flare-up
- Have used steroid creams for 3 days or more in the last 8 weeks. This does not have to be 3 days in a row.

You **cannot** take part if:

- You ONLY have eczema on the scalp and/or at sensitive body sites like your face, armpits or groin
- Your eczema is ONLY in places where your skin is in contact with nickel, e.g. jewellery
- Your eczema is ONLY around varicose veins or ONLY on your hands
- You are taking part in another eczema study where you are trying something new for your eczema like a treatment or medicine
- Someone else from your household is already taking part in the Keep Control of Eczema Study
- You use the very strong steroid cream clobetasol propionate 0.05% (trade name Dermovate).
- You use a steroid cream that includes antibiotics or antifungals (if you are not sure you can check **here**

If you are under 16 years old, your parent/carer will need to agree that you can take part.

2. Who has set up the study?

People living with eczema, along with parents of children with eczema, have teamed up with researchers from the University of Nottingham.

Together, they are trying to find out how long to treat eczema flare-ups for.

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The Keep Control of Eczema Study is part of the Rapid Eczema Trials project (www.RapidEczemaTrials.org). This project is funded by the National Institute for Health and Care Research (NIHR) and sponsored by Nottingham University Hospitals NHS Trust.

3. Do I have to take part?

No, it's up to you whether to take part in this study. If you have any questions about taking part, you can contact us and we will try and answer them: RapidEczemaTrials@nottingham.ac.uk

4. What will I have to do if I take part?

Step 1
Answer some questions online about you and your eczema to find out if you are able to take part in the Keep Control of Eczema Study.

You will then complete an online consent form to say that you are happy to take part. If you are aged under 16 years, your parent/carer will need to complete the consent form.

Step 2
You will be randomly placed into one of two groups:

- **Specific advice group**: people in this group will be given advice to treat their eczema flare-ups for slightly longer.
- **Treat as usual group**: people in this group will be given advice to treat their eczema as usual.

This means you will not be able to choose which group you are in, to make sure our study is a fair test.

We will send you advice on how to treat your eczema flare-ups while you are in the study.

Step 3
Follow the flare-up treatment advice you have been given and continue in the study for 4 months. You can use your usual eczema treatments that have either been prescribed by your doctor or you have bought from a pharmacy.

We will email or text you a link to answer some questions about your eczema each week for 4 months. Your weekly responses are really important for the study.

If you are happy to, you can take and upload photos of your eczema twice during the study. You do not have to agree to taking and uploading any photos if you would prefer not to.

Everything we ask you to do will be online. This means you can access it with your computer or smartphone/tablet from home. You will not be asked to attend any healthcare appointments as part of this study.

We ask that you do not start any new eczema treatments during the study, if possible. If you do change your eczema treatments, please stay in the study. It is helpful for us to know what has changed, so we will ask you about this in your study questionnaires.

We will send you reminders by email or text when the questionnaires need completing. We may also give you a friendly call as a reminder to fill in the questionnaires, or to collect the information from you over the phone.

Children may fill in the questionnaires themselves if they are able to, or with the help of an adult. A parent/carer can complete the questionnaire on behalf of a child, but we encourage you to discuss the answers with your child (if appropriate). If an adult is completing the questions on behalf of a child, this should be the same adult for the whole study if possible.

Everyone who completes the final study questionnaire at 4 months can enter a prize draw if they would like to.

You may also be asked if you would be willing to talk to a researcher about your experience of being in the study. You do not have to agree to doing this is you would prefer not to.

5. What are the benefits to taking part?

We hope this study will help people with eczema to understand how best to manage their eczema.

Some people like to feel they are helping others by taking part, and some people like to try new things out for themselves.

If you would like to, you can enter the prize draw as a thank you for taking part. You could win £20 or a child-friendly book about living with eczema. Each questionnaire you complete during the study will give you an entry into the prize draw. For example, if you complete all 16 weekly questionnaires, you will be entered 16 times.

6. What are the risks of taking part?

It is possible that some people may find their eczema gets better but some might find that it gets worse. You can still use your regular creams and treatments to help improve the symptoms and speak to your usual healthcare professionals if you need to.

Steroid creams are very safe if used for short periods of time to treat eczema flare-ups.

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If the eczema has not improved after using the steroid creams for 14 days in a row, or if you are worried about your eczema, you should discuss your eczema with a healthcare professional.

Because skin on the face, armpits and groin is more sensitive, you will not be asked to change how you treat your eczema in these places. You should treat eczema in these areas as you normally would.

Steroid creams can have side-effects if used for long periods of time without having a break in treatment. We don't expect you to experience side-effects any differently to usual while taking part in this study.

Your safety is always our priority. We do not think you are likely to come to any harm in this study, but if you experience any problems, you can contact the study team on: RapidEczemaTrials@nottingham.ac.uk

7. If I choose to provide photos what will happen to them?

If you choose to provide photos you will be given information on how to take and safely upload them. You will need access to a device that can take and upload photos, like a smartphone or tablet. We will ask you to take and upload photos twice during the study.

You won't be asked to take photos of private or sensitive areas of the body. Some photos may contain features that could identify you e.g. your face, scarring, birthmarks, body art, piercing. You can decide whether you are happy to take and upload these photos or not. If you have eczema on the face, you might like to take a close-up of the eczema rather than showing the whole face.

You will upload the photos to a secure web platform, hosted by Imperial College London. We'll put the photos into a computer program that will score how your eczema is at the moment. This computer program has been developed using artificial intelligence (AI) technology. It has been trained to assess the severity of eczema using photos from hundreds of people with eczema, including people of all skin tones. This program assesses the common features of eczema, so that it can estimate how severe the eczema is from photos. The computer program will provide a score for each photo that you upload but we will not be able to return the scores to you. This is because the system is still new and being tested, so we're not sure how well it can score your eczema just yet. The scores will be shared securely between Imperial College London and the University of Nottingham for analysis.

Your photos may also be viewed and scored by a member of the research team who is trained to assess eczema. The assessor scores will be compared with the scores from the computer program.

Your photos will be assigned a code number, this means that nobody can identify you personally from the photos assuming there are no identifiable features present in the photo. We'll keep all information about you safe and secure. The photos will be shared with

the research team at the University of Nottingham and the sponsor of the study (Nottingham University Hospitals NHS Trust).

We may share some of the data or photos that you provide with other researchers. Whilst we will do our best to ensure you cannot be identified from this data, we cannot guarantee this if the photos contain features that may identify you. We will not use images in public without your permission.

You may need to store photos of your eczema on your mobile device before you can upload them to the secure web platform. It will be up to you to delete them after uploading your photos if you do not want to store them there.

8. What if I'm worried about extra costs from taking part in the study?

We don't think that taking part in this study will increase your costs. If you find you are using more steroid cream than usual, it might be helpful to buy a Prescription Prepayment Certificate that allows you to have additional prescriptions without extra costs.

With a Prescription Prepayment Certificate, you will save money if you need more than 3 items in 3 months, or 11 items in 12 months.

You can find out more about this at: https://www.nhsbsa.nhs.uk/help-nhs-prescription-costs/nhs-prescription-prepayment-certificate-ppc

9. What will happen if I don't want to carry on with the study?

If you change your mind at any time and don't want to carry on in the study, that is OK. It is up to you if you want take part. If you decide you don't want to carry on, we will still keep and use the information collected before you stopped taking part.

If you are unsure about whether to continue at any stage, then please contact us here: RapidEczemaTrials@nottingham.ac.uk

10. What happens at the end of the study?

When your time in the study ends after 4 months, you can go back to treating your eczema as you normally would.

Once the Keep Control of Eczema Study has finished for all participants, we will share the results with everyone who took part. We will also put the results on the Rapid Eczema Trials website.

The results will also be published in scientific medical journals, presented at conferences, and shared with the wider eczema community.

You might like to sign-up to the Rapid Eczema Trials newsletter to receive regular updates about the whole Rapid Eczema Trials project: www.RapidEczemaTrials.org

11. How to contact us

You can contact the Keep Control of Eczema Study research team here: RapidEczemaTrials@nottingham.ac.uk

11. Who is organising and funding this study? How has it been approved?

The study is being organised by Nottingham University Hospitals NHS Trust (the Sponsor) and is coordinated by the University of Nottingham. The study is funded by the National Institute for Health and Care Research (NIHR). All research involving people is checked by an independent group of people, called a Research Ethics Committee. This study has been approved by London-Surrey Research Ethics Committee (23/PR/0899) Research Ethics Committee.

People with eczema have worked as citizen scientists and identified **how best to keep control of eczema** as a question that is important to them. They have worked in teams with researchers and doctors to help design important parts of this study. People with experience of eczema are also involved in the teams that oversee the running of the study.

I want to take part in the study! What do I do now?

If you would like to take part, click the 'Join Now' button on our website: https://rapideczematrials.org/keep-control-study/

If you have any difficulties, please contact the Keep Control of Eczema Study team: RapidEczemaTrials@nottingham.ac.uk

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How will information about me be used?

We will need to use information from you for this research project.

This information will include

- Your name
- Your contact details
- Information about you and your eczema
- Photos of your eczema (if you choose to upload them).

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.

Nottingham University Hospitals NHS Trust, University of Nottingham and Imperial College London are joint data controllers for this study and are responsible for looking after your information.

We will keep all information about you safe and secure by:

- Following and adhering to the laws relating to General Data Protection Regulation (GDPR)
- Storing your data and photos on a secure platform at Imperial College London, at the University of Nottingham and at Nottingham University Hospitals NHS Trust
- Using a secure, encrypted transfer protocol when transferring your data
- Having strict access controls on our electronic systems
- Deleting your personal data (as outlined in this information sheet) when it is no longer required
- Keeping the details we have to contact you separate from the trial data

If you choose to provide photos of your eczema, they might include features that may identify you. This could be scarring, birthmarks, body art, piercing etc.

If you choose to provide your phone number, we will share your name and telephone number with Esendex, our text messaging provider and their sub processors. They will use this information to send you text message reminders about the study questionnaires whilst you are taking part in the study. Esendex will keep the information shared with them for two years or until the end of the RAPID Eczema Trials Project (whichever occurs first) before it is destroyed. You can choose to share your phone number for study-related communication, but it's okay if you don't. You can still take part either way.

In accordance with Sponsor, Government and funder policies we may share data about you within and outside the UK for research related purposes to:

- Enable researchers to re-use data for new questions.
- Check our findings to ensure accuracy and reliability.

This means that they don't waste time and resources repeating the same work.

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- Some of the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- We use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information

Commissioner's Office (ICO) website

- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website

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.

We will keep your study data for a minimum of 5 years after the end of the study as per sponsor policy.

The study data will then be fully anonymized and securely archived or destroyed.

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.

You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Where can you find out more about how your information is used?

Nottingham University Hospitals NHS Trust, University of Nottingham and Imperial College London are joint data controllers for this study. This means they are jointly responsible for how your data is being processed. You can find out more about how we use your information:

- For Nottingham University Hospitals NHS Trust at https://www.nuh.nhs.uk/data-patients-public
- For Imperial at https://www.imperial.ac.uk/admin-services/secretariat/university-governance-and-key-documents/privacy-notices/
- For Imperial at https://www.imperial.ac.uk/research-and-innovation/research-office/research-governance-and-integrity/what-is-research-governance/data-protection---information-for-participants/
- For University of Nottingham at https://www.nottingham.ac.uk/utilities/privacy/privacy.aspx

- www.hra.nhs.uk/patientdataandresearch
- http://www.nctu.ac.uk/data-protection/data-protection.aspx
- by sending an email to: RapidEczemaTrials@nottingham.ac.uk
- by calling the Nottingham Clinical Trials Unit on (0115) 8231600

FUNDED BY

NIHR | National Institute for Health and Care Research

This project is funded by the National Institute for Health and Care Research (NIHR) under its Programme Grants for Applied Research programme (PGfAR NIHR203279). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care

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