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Keep Control of Eczema Study

Submission date
03/04/2025

Recruitment status
Recruiting

Registration date
06/05/2025

Overall study status
Ongoing

Last Edited
10/02/2026

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is part of the Rapid Eczema Trials project. The project hopes to answer many questions about how to look after eczema. People with eczema are helping to design and run these studies. This means that the project will answer important questions for people with eczema.Eczema is a long-term skin condition that causes itching and goes through cycles of flare-ups and remission. People with eczema can usually manage it themselves by applying treatments directly to their skin. These treatments include corticosteroid ("steroid") creams, which are the main way to control flare-ups. Advice given by healthcare professionals on how long to use steroid creams can often be vague, with instructions like "use sparingly" or "use as needed". This uncertainty is partly due to a lack of research on the best approach. In this Keep Control of Eczema Study, the researchers will test if providing specific advice on how long to use a corticosteroid ("steroid") cream for during a flare-up can help keep eczema controlled for longer compared to no specific advice.

Who can participate?
Patients aged 1 year and older who already use steroid creams to manage their eczema can join the study. The researchers are encouraging people from different backgrounds to take part.

What does the study involve?
People will join the study by signing up on the study's website. They will give information about their eczema and how they currently treat their eczema flare-ups. They will then be put into one of two groups at random. One group will be given specific advice about how long to use their steroid creams for when they have an eczema flare-up. The other group will be asked to use steroid creams during a flare-up as they normally would.

People will be asked to follow their advice strategy for 16 weeks. They will be asked to complete some questions, sent to them by email/text message each week. People will be able to upload photos of their eczema if they would like to. These photos will be put through a computer programme that has been trained to assess eczema severity from photos to explore the accuracy of this approach. People can take part from home and do not need to travel.

As soon as the study results are known, they will be shared as quickly as possible on the study's website (www.RapidEczemaTrials.org).

What are the possible benefits and risks of participating?
The study aims to help people with eczema 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.

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

Steroid creams are very safe if used for short periods to treat eczema flare-ups. However, they can have side effects if used for long periods of time without having a break in treatment. Participants are not expected to experience side effects any differently than usual while taking part in this study. If the eczema has not improved after using the steroid creams for 14 days in a row, or if they have concerns, participants are advised to discuss their eczema with a health care professional.

Where is the study run from?
The study is being organised by Nottingham University Hospitals NHS Trust (the Sponsor) and is coordinated by the University of Nottingham. Participants join the study online and take part from home, so they can live anywhere within the UK.

When is the study starting and how long is it expected to run for?
September 2022 to October 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
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Contact information

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Public

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Additional identifiers

Integrated Research Application System (IRAS)
329123

Central Portfolio Management System (CPMS)
58276

Study information

Scientific Title
Impact of providing specific advice on how long to apply topical corticosteroids (TCSs) for during an eczema flare-up, compared to no specific advice on disease control, eczema symptoms and quality of life in children and adults with eczema: an online, superiority randomised controlled trial

Acronym
Keep Control of Eczema Study

Study objectives
Does providing specific advice on how long to apply topical corticosteroids (TCSs) for during an eczema flare-up improve eczema control compared to no specific advice over 4 months?

This study is part of the Rapid Eczema Trials project (https://www.isrctn.com/ISRCTN12016473), which aims to answer many questions about how to manage eczema through the delivery of multiple, online clinical trials (www.rapideczematrials.org). An "Eczema Research Community" of people with eczema is helping to prioritise, design and run these studies. This means that the project will answer important questions for people with eczema.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 30/05/2025, London - Surrey Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)207 1048088; surrey.rec@hra.nhs.uk), ref: 23/PR/0899

Study design
Pragmatic two-arm parallel-group, superiority randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life, Treatment

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

Interventions
The study is an “advice trial” testing two advice strategies:

Specific advice on duration of applying topical corticosteroids (TCS) (treat flare-ups for longer):
• Use of TCS during a flare-up and for 2 days after the skin is eczema-free.

No specific advice on duration of applying TCS (treat flare-ups as usual):
• Use of TCS during a flare-up as the participant normally would.

Randomisation will be carried out by the participant using a secure, online randomisation system. Participants will be randomised 1:1 to either the intervention group (specific advice) or the control group (treat flare-ups as usual) using a minimisation algorithm with a probabilistic element balancing on the following factors:
• Eczema severity POEM score (0-7 mild, 8-16 moderate, 17-28 severe).
• Age (<4 years, 4-11 years, 12-15 years, 16-25 years, 26-55 years, >55 years)
• Potency of TCS (mild, moderate, potent)

Following randomisation, participants will be provided with intervention instructions detailing how long they should treat their eczema flare-up for according to their allocation. Participants should follow this advice when they have a flare-up during the 4 months they are in the study.

Participants will be advised to use their usual prescribed TCS and will remain under the care of their usual healthcare professional.

Intervention Type
Behavioural

Primary outcome(s)
Eczema control is measured using the Recap of atopic eczema (RECAP) questionnaire, which includes 7 items (scored 0 to 28) assessed weekly over 16 weeks

Key secondary outcome(s))
1. Eczema symptoms measured using the Patient Oriented Eczema Measure (POEM), which includes 7 items (scored 0 to 28), assessed monthly
2. Total days of topical corticosteroids (TCS) used (days of TCS use each week during 0 to 7 days)

measured using a questionnaire weekly
3. Skin-specific quality of life measured using the Infants' Dermatitis Quality of Life Index (IDQoL) (under 4 years), Children's Dermatology Life Quality Index (CDLQI) (from 4 years to 15 years) or Dermatology Life Quality Index (DLQI) (16 years and over) – 10 items, scored 0 to 30, at baseline and week 16
4. The number of weeks when TCS were not used measured using data collected from the use of TCS questions assessed by questionnaire weekly, at one timepoint
5. The number of well-controlled weeks, defined as the number of weeks with Recap score <6, measured using data collected from the RECAP questionnaire, at one timepoint
6. Global change in eczema from baseline measured using data collected from the POEM questionnaire at week 16
7. Adverse events measured using a questionnaire which records the following monthly:
7.1. Contact with a healthcare professional (HCP) because of a worsening of the eczema
7.2. Contact with HCP due to concerns about side effects

Additional information will be collected to inform the analysis and interpretation of the trial, including:
1. Minimisation variables, prior belief in intervention strategy, demographics, UK Diagnostic Criteria for Eczema measured using a questionnaire at baseline only
2. Potency of TCS currently used on body, number of days TCS used to treat last flare-up, use of TCS to prevent flare-ups, strategy for starting TCS, attitudes towards use of TCS, sensory issues that might influence use of eczema treatments, use of systemic eczema medications (not including antihistamine), use of other steroid formulations (for any condition) measured using a questionnaire at baseline only
3. Flares used to assess adherence measured using a questionnaire monthly
4. Intervention group only - adherence to advice about TCS duration of use measured using a questionnaire monthly
5. Changes in eczema treatments measured using a questionnaire monthly

Completion date
31/10/2026

Eligibility

Key inclusion criteria
1. Aged ≥1 year with self-report of eczema(syn. Atopic dermatitis, atopic eczema)
2. Used topical corticosteroid on a total of at least 3 days to manage eczema flare-up in the last 8 weeks
3. Willing to change how currently using TCS treatments whilst in the trial
4. Usual residence in the UK
5. Able and willing to give informed consent (or parent/legal guardian able and willing to give informed consent for children under 16 years)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
1 years

Upper age limit
120 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Using a TCS preparation that includes antibiotics or antifungal (and have no other TCS available), as these products are not intended for long-term use.
2. Diagnosis unlikely to be atopic eczema: only present on hands (likely to be hand eczema or contact dermatitis); limited to locations where skin is exposed to nickel, e.g. jewellery (likely to be contact dermatitis); eczema only around varicose veins (likely to be varicose eczema).
3. Taking part in another eczema intervention trial.
4. Member of household already participating in this trial.
5. Eczema only present on the scalp (as this requires different topical steroid formulations) and /or only at sensitive body sites (e.g. groin, armpits or face (as the advice being tested is not applicable to treatment at sensitive sites, which may require a different potency and duration of treatment)).
6. Using TCSs classed as super potent (i.e. Dermovate, clobetasol propionate 0.05%) - to ensure participant safety.

Date of first enrolment
15/07/2025

Date of final enrolment
08/06/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
All recruitment will take place online via the Rapid Eczema Trials website
https://rapideczematrials.org/
-
England
NG7 2RD

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Nottingham Clinical Trials Unit (NCTU) (ctu@nottingham.ac.uk) in accordance with NCTU's data sharing procedure. Access to the data will be subject to review of a data sharing and use request by a committee, including the CI and sponsor and will only be granted upon receipt of a data sharing and use agreement. Any data shared will be de-identified. Consent from participants to share data was obtained.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 4.0	29/04/2025	17/07/2025	No	No
Protocol file	version 4.1	10/09/2025	10/02/2026	No	No
Protocol file	version 4.2	14/01/2026	10/02/2026	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes