

# Best emollients for eczema

<b>Submission date</b> 08/05/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 05/06/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/11/2023	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Current plain English summary as of 12/08/2019:

### Background and study aims

Eczema is a common childhood condition where the skin is dry and itchy. It is usually diagnosed in the first two years of life and in the UK most children are treated by their GP. Moisturisers (emollients) are the main treatment for eczema, but there are many types and we do not know whether one is better than another. The aim of this study is to investigate the effectiveness and acceptability of the main types of emollients - lotion, cream, gel and ointment - in children with eczema to find out which works best.

### Who can participate?

Children aged six months to twelve years old who have eczema

### What does the study involve?

Participants are randomly allocated into one of four groups. Those in the first group are provided with lotion, those in the second with cream, those in the third with gel, and those in the fourth with ointment. Prescriptions are issued with directions to apply twice daily and as required, and participants are advised to use their allocated treatment as the only leave-on emollient for 16 weeks. After this time, participants can continue to use their allocated emollient or switch to another one. At the start of the study and then after 16 and 52 weeks, participants undergo an examination to see if their eczema has improved.

### What are the possible benefits and risks of participating?

Using the study moisturiser as recommended may improve the symptoms of eczema for participants. However, this cannot be guaranteed. There is a risk that participants may experience side effects from using the moisturisers (e.g. skin reactions related to their use, possible slips or falls due to use). In addition, participants may either not like the emollient they are given and/or it may not be helpful for their eczema.

### Where is the study run from?

GP practices in Clinical Research Networks (CRNs) - West of England, Wessex and East Midlands (UK)

When is the study starting and how long is it expected to run for?

May 2017 to May 2021 (updated 17/02/2021, previously: February 2021 (updated 18/03/2020, previously: June 2021))

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Ms Sian Wells

bee-study@bristol.ac.uk

Previous plain English summary:

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Where is the study run from?

25 GP practices in Clinical Research Networks (CRNs) located in Bristol, Southampton and Nottingham (UK)

When is the study starting and how long is it expected to run for?

May 2017 to August 2020

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Ms Sian Wells

bee-study@bristol.ac.uk

# Contact information

## Type(s)

Public

## Contact name

Ms Sian Wells

## ORCID ID

<https://orcid.org/0000-0002-5334-7599>

## Contact details

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# Additional identifiers

## Clinical Trials Information System (CTIS)

2017-000688-34

## Integrated Research Application System (IRAS)

214900

## Protocol serial number

34197

# Study information

## Scientific Title

The Best Emollients for Eczema (BEE) trial: a randomised trial comparing the effectiveness of four types of commonly prescribed emollients for children with eczema

## Acronym

BEE

## Study objectives

The aim of this study is to investigate the effectiveness and acceptability of the main types of emollients - lotion, cream, gel and ointment - in children with eczema.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

## **Study design**

Randomized; Interventional; Design type: Treatment, Drug

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Atopic dermatitis

## **Interventions**

Current version as of 03/04/2018:

Participants are randomised to one of the four intervention groups: Lotion, Cream, Gel or Ointment. Randomisation will be according to a 1:1:1:1 ratio, stratified by centre and minimised by baseline eczema severity (mild versus moderate/severe) and participant age (less than 2 years old versus 2 years and above).

Prescriptions will be issued with directions to apply twice daily and as required, and participants are advised to use their allocated emollient as the only leave-on emollient for 16 weeks. Beyond 16 weeks, participants can continue to use their allocated emollient or switch to another one. Clinical management of eczema will otherwise be as usual – with treating clinicians and participants free to make clinic appointments, referrals and to continue to use or change other treatments (including topical corticosteroids) as normal.

Follow-up for all study arms is 52 weeks.

Original version:

Participants are randomised to one of the four intervention groups: Aveeno® lotion, Diprobase® cream, Doublebase® gel or Epaderm® ointment. Randomisation will be according to a 1:1:1:1 ratio, stratified by centre and minimised by baseline eczema severity (mild versus moderate/severe) and participant age (less than 2 years old versus 2 years and above).

Prescriptions will be issued with directions to apply twice daily and as required, and participants are advised to use their allocated emollient as the only leave-on emollient for 16 weeks. Beyond 16 weeks, participants can continue to use their allocated emollient or switch to another one. Clinical management of eczema will otherwise be as usual – with treating clinicians and participants free to make clinic appointments, referrals and to continue to use or change other treatments (including topical corticosteroids) as normal.

Follow-up for all study arms is 52 weeks.

## **Intervention Type**

Other

## **Phase**

Phase IV

## **Primary outcome(s)**

Parent-reported eczema symptoms measured using the Patient-Oriented Eczema Measure (POEM) weekly for 16 weeks.

## **Key secondary outcome(s)**

1. Parent-reported eczema symptoms are measured by the Patient Oriented Eczema Measure (POEM), monthly for 52 weeks
2. Eczema signs are assessed using the Eczema and Area Severity Index (EASI), by blinded assessor at baseline and 16 weeks
3. Parent-reported use of study emollient/other eczema treatments are measured with items constructed for the study, weekly for 16 weeks and then monthly until 52 weeks
4. Satisfaction with study emollient is assessed with items constructed for the study (parent /participant self-report) at 16 weeks
5. Adverse effects (localised reactions – such as itching, burning, redness/inflammation, pain, skin infections – and slips and falls) are assessed with items constructed for the study (parent /participant self-report), weekly for 16 weeks and then monthly until 52 weeks
6. Parent-reported personal costs and healthcare contacts are measured with items constructed for the study monthly until 52 weeks, while further healthcare professional contacts and prescriptions of relevant treatments are collected from participant's electronic medical record (EMR) after 52 weeks
7. The impact of eczema on participants' quality of life is measured using the Atopic Dermatitis Quality of Life (ADQoL) questionnaire at baseline, 6, 16 and 52 weeks
8. The quality of life of participants is assessed using the Child Health Utility 9D ( CHU-9D) at baseline, 6, 16 and 52 weeks
9. The impact of the participant's eczema on the family's quality of life is measured using the Dermatitis Family Impact (DFI) questionnaire at baseline, 16 and 52 weeks
10. Acceptability of study emollients and study procedures are measured with items constructed for the study (parent/participant self-report of acceptability at baseline and 16 weeks, and of study procedures at 52 weeks) and with semi-structured qualitative interviews (approximately 2-4 weeks post-randomisation and after 16 weeks)

## **Completion date**

31/05/2021

## **Eligibility**

### **Key inclusion criteria**

Children:

1. Aged between 6 months and less than 12 years of age
2. Have eczema diagnosed by an appropriately qualified healthcare professional (registered doctor, nurse or health visitor)
3. Have mild eczema or worse (POEM score >2)

Person giving consent:

1. Have parental responsibility for the participant
2. Willing to use the randomly allocated emollient as the only leave-on emollient for 16 weeks.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

6 months

**Upper age limit**

12 years

**Sex**

All

**Total final enrolment**

550

**Key exclusion criteria**

Child:

1. Known sensitivity to study emollients or their constituents
2. Participating in another research study currently or in the last four months
3. Any other known adverse medical or social circumstance that would make invitation to the study inappropriate (as determined by GP practice staff)

The person giving consent:

1. Unable to give informed consent
2. Insufficient written English to complete outcome measures.

**Date of first enrolment**

01/01/2018

**Date of final enrolment**

31/10/2019

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**NIHR CRN West of England**

Whitefriars

Lewins Mead

Bristol

United Kingdom

BS1 2NT

**Study participating centre**  
**NIHR CRN Wessex**  
Unit 7  
Berrywood Business Village  
Tollbar Way  
Hedge End  
Southampton  
United Kingdom  
SO30 2UN

**Study participating centre**  
**NIHR CRN East Midlands**  
First Floor  
Knighton Street Outpatients Building  
Leicester Royal Infirmary  
Leicester  
United Kingdom  
LE1 5WW

## **Sponsor information**

**Organisation**  
University of Bristol

**ROR**  
<https://ror.org/0524sp257>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
National Institute for Health 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 stored in a publicly available repository (the University of Bristol data repository).

## IPD sharing plan summary

Stored in publicly available repository

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		23/05/2022	26/05/2022	Yes	No
<a href="#">Results article</a>		01/10/2023	06/11/2023	Yes	No
<a href="#">Protocol article</a>	protocol	06/11/2019	17/02/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Parent/Carer Consent Form and Assent Form for children version 3.0	03/11/2017	11/07/2023	No	Yes
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes