

# Barrier Enhancement for Eczema Prevention

<b>Submission date</b> 25/07/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 25/07/2014	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/07/2024	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Children born into families with a history of eczema, asthma or hay fever are more likely to develop eczema. We want to find out if applying moisturisers every day for the first year of life will make a difference to whether children will develop eczema or not.

### Who can participate?

Babies who are less than 3 weeks old and who have a direct relative diagnosed with eczema, allergic rhinitis or asthma.

### What does the study involve?

If you decide to take part, you will be randomly allocated to either best practice skin care routine for your baby or best practice skin care routine including applying moisturiser to your baby at least once a day for a year. The moisturiser will be provided free of charge. You will be asked to complete some short questionnaires which will be sent and returned either online or by post and you will see a researcher just after your babys second birthday to assess whether they have developed eczema.

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

There is very little risk involved in taking part and we dont expect to discover any new side-effects of the skin care advice. Taking part in this study will take up some of your time as you will need to follow the skin care advice until your baby is 1 year old and complete the questionnaires every 3, 6 or 12 months until your child is 5 years old. For those receiving the advice to also apply the moisturiser for a year, there is a low risk that this could cause skin infections because it may block the pores in the skin.

### Where is the study run from?

16 sites around the England are involved in running the study, it is being co-ordinated from the Nottingham Clinical Trials Unit in collaboration with the Centre of Evidence Based Dermatology.

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

November 2014 to October 2021

### Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?  
Dr Laura Wyatt  
beep@nottingham.ac.uk

**Study website**

<http://beepstudy.org/>

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Laura Wyatt

**Contact details**

Nottingham Clinical Trials Unit  
Applied Health Research Building  
School of Medicine  
University of Nottingham  
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United Kingdom  
NG7 2RD  
+44 (0)115 823 2435  
beep@nottingham.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

149888

**ClinicalTrials.gov number**

**Secondary identifying numbers**

16940; HTA 12/67/12

## Study information

**Scientific Title**

A randomised controlled trial to determine whether application of emollient from birth for a year, can prevent eczema in high-risk children

**Acronym**

BEEP

**Study objectives**

The purpose of the trial is to determine whether advising parents to apply emollient to their child for the first year of life in addition to best practice infant skin care advice can prevent or delay the onset of eczema.

Updated 04/01/2019:

A copy of the trial protocol, statistical analysis plan and health economics analysis plan can be found at: <https://www.journalslibrary.nihr.ac.uk/programmes/hta/126712/#/documentation>

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

14\WM\0162; First MREC approval date 09/06/2014

### **Study design**

Randomised; Interventional; Design type: Prevention

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

GP practice

### **Study type(s)**

Prevention

### **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

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

Topic: Children, Primary Care, Dermatology; Subtopic: All Diagnoses, Not Assigned, Skin (all Subtopics); Disease: Dermatology, All Diseases, All Diseases

### **Interventions**

Participants are randomised to the intervention group will, in addition, be advised to apply emollient daily to the child's entire body surface area for the first year of life. Parents of children in the intervention group will be given a choice of two emollients (Doublebase Gel® and Diprobase Cream®) and may change between the two emollients throughout the trial if they wish. Families will be seen at around the time of the child's second birthday to collect the primary outcome data, and then followed up for a further 3 years after this. During this time, we will ask parents to complete nine questionnaires at the start of the study and then at 3, 6, 12, 18, 24, 36, 48 and 60 months. The questionnaires will include questions about any skin problems, eczema, wheezing, hayfever-like or food allergy symptoms or diagnosis, visits to the doctors and prescriptions, use of skin and wash products, feeding and your quality of life.

### **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

Primary outcome measure as of 08/12/2016:

Diagnosis of eczema between 12 and 24 months of age defined as meeting the UK Working Party Diagnostic criteria).

Original primary outcome measure:

Parent reported - UK Working Party Diagnostic Criteria for atopic dermatitis; Timepoint(s): 12 & 24 months

## **Secondary outcome measures**

Secondary outcome measures as of 08/12/2016:

1. Presence of eczema between birth and 24 months is assessed using:
  - 1.1. Any parental report of a clinical diagnosis of eczema
  - 1.2. Completion by parents of UK Working Party Diagnostic Criteria for Atopic Dermatitis at 12 and 24 months
2. Presence of visible eczema at 24 months (skin examination by researcher)
3. Time to onset of eczema is assessed using:
  - 3.1. First parental report of a clinical diagnosis of eczema
  - 3.2. First topical corticosteroid and /or immunosuppressant prescription for eczema
4. Severity of eczema is assessed using EASI at 24 months and POEM\*at 12 and 24 months
5. Presence of other allergic diseases:
  - 5.1. Parental reported wheezing and allergic rhinitis between 12 and 24 months
  - 5.2. Parental report of a clinical diagnosis of food allergy at 12 and 24 months
  - 5.3. Parental report of food allergy at 12 and 24 months. Parents will be specifically questioned about cow's milk, egg, peanuts, and other nuts plus "any other food".
  - 5.4. Allergic sensitisation at 24 months to any of the following common allergens: milk, egg, peanut, cat, grass pollen, house dust mite.
  - 5.5. Confirmed diagnosis of food allergy at 24 months to milk, egg, peanut or 'any of milk, egg or peanut'. The diagnosis is derived from a combination of parental report, allergic sensitisation and food challenge.
6. Health-related quality of life is measured using CHU-9D at 24 months in order to estimate QALYs and parental quality of life measured using the EQ-5D-5L at baseline and 24 months in order to estimate the change in parental QALYs, if any
7. Health economic outcomes:
  - 7.1. Health care resource use at 3, 6, 12, 18 and 24 months.
  - 7.2. Cost-effectiveness and cost-utility at 24 months (combining health resource use and health-related quality of life outcomes).

Original secondary outcome measures:

1. EASI - Eczema Area and Severity Index; Timepoint(s): 24 months
2. EQ5D-5L - Parental quality of life; Timepoint(s): Baseline and 24 months
3. IDQoL - Infant Dermatitis Quality of Life; Timepoint(s): 24 months
4. POEM - Patient-oriented eczema measure; Timepoint(s): 12 and 24 months

Added 01/02/2022:

Tertiary outcome measures\*

1. Presence of eczema in the previous year at 36, 48 and 60 months based on parental report of a clinical diagnosis of eczema

2. Any parental report that in their opinion their child has eczema at 3, 6, 12, 24, 36, 48 and 60 months
3. Presence of eczema at 36, 48 and 60 months based on completion by parents of UK Working Party Diagnostic Criteria for Atopic Dermatitis
4. Severity of eczema at 36, 48, and 60 months as measured by POEM
5. Parental reported wheezing, at 36, 48 and 60 months
6. Parental reported allergic rhinitis at 36, 48 and 60 months
7. Parental reported food allergy symptoms at 36, 48 and 60 months
8. Parental report of a clinical diagnosis of asthma or allergic rhinitis by 60 months
9. Parental report of a clinical diagnosis of food allergy at 36, 48 and 60 months
10. CHU-9D at 36, 48 and 60 months in order to estimate QALYs
11. Parental quality of life measured using EQ-5D-5L at 36, 48 and 60 months in order to estimate parental QALYs
12. Health care resource use at 36, 48 and 60 months
13. Cost utility and cost-effectiveness at 60 months (combining health resource use and health-related quality of life outcomes)
14. Parental report of clinical diagnosis of eczema from the age of 12 months to 60 months
15. Parental report of clinical diagnosis of food allergy by 60 months

\*Details of the analyses of the tertiary outcomes were added by the trial statistician after the analysis of the primary and secondary outcomes at which point, the investigators, trial management, data management and statisticians were aware of the results.

**Overall study start date**

01/11/2014

**Completion date**

30/10/2021

## Eligibility

**Key inclusion criteria**

Inclusion criteria as of 08/12/2016:

1. Child has a first degree relative with parental reported doctor diagnosis of eczema, allergic rhinitis or asthma.
2. Child up to 21 days old.
3. Mothers must be aged  $\geq 16$  years
4. Consenting adult has the ability to understand English.

Original inclusion criteria:

1. Child has a first-degree relative with parental reported doctor diagnosis of eczema, allergic rhinitis or asthma
2. Child in overall good health
3. Child up to three weeks old
4. Consenting adult has the ability to understand English

**Participant type(s)**

Patient

**Age group**

Neonate

**Sex**

Both

**Target number of participants**

Maximum of 1400 children

**Total final enrolment**

1394

**Key exclusion criteria**

Exclusion criteria as of 08/12/2016:

1. Preterm birth (defined as birth prior to 37 weeks gestation)
2. Sibling (including twin) previously randomised to this trial. If multiple birth the first child will be randomised into the trial
3. Child has a severe widespread skin condition that would make the detection and/or assessment of eczema difficult
4. Child has a serious health issue which, at parent or investigator discretion, would make it difficult for the family to take part in the trial
5. Any condition that would make the use of emollient inadvisable or not possible

Original exclusion criteria:

1. Preterm birth (defined as birth prior to 37 weeks gestation)
2. Sibling (including twin) previously randomised to this trial
3. Child has serious health issues or a severe widespread skin condition
4. Any condition that would make the use of emollient inadvisable or not possible

**Date of first enrolment**

01/11/2014

**Date of final enrolment**

30/11/2016

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre****Centre of Evidence-Based Dermatology**

University of Nottingham

C Floor, South Block

Queen's Medical Centre

Nottingham University Hospitals NHS Trust

Nottingham

United Kingdom

NG7 2UH

**Study participating centre**

**St Mary's Hospital**

Dermatology Dept  
Milton Road  
Portsmouth  
United Kingdom  
PO3 6AD

**Study participating centre**

**Harrogate District Hospital**

Lancaster Park Road  
Harrogate  
United Kingdom  
HG2 7SX

**Study participating centre**

**Kings Mill Hospital**

Mansfield Road  
Sutton in Ashfield  
United Kingdom  
NG17 4JL

**Study participating centre**

**Queen's Hospital**

Burton Hospitals NHS  
Belvedere Road  
Burton upon Trent  
United Kingdom  
DE13 0RB

**Study participating centre**

**Derby Children's Hospital**

Royal Derby Hospital  
Uttoxeter Road  
Derby  
United Kingdom  
DE22 3NE

**Study participating centre**

**Leicester Royal Infirmary**  
Infirmary Square  
Leicester  
United Kingdom  
LE1 5WW

**Study participating centre**  
**York Hospital**  
Wiggington Road  
York  
United Kingdom  
YO31 8HE

**Study participating centre**  
**University of Sheffield**  
K Floor  
The Medical School (RHH tower)  
Beech Hill Road  
Sheffield  
United Kingdom  
S10 2RX

**Study participating centre**  
**St Mary's Hospital**  
Imperial College Healthcare NHS Trust  
London  
United Kingdom  
W2 1NY

**Study participating centre**  
**Francis Grove Medical Practice**  
Wimbledon  
London  
United Kingdom  
SW19 4DL

**Study participating centre**  
**Streatham Common Medical Practice**  
St Andrew's Church room  
Guildersfield Road  
London



United Kingdom  
SW16 5LS

**Study participating centre**  
**Clapham Park Group Practice**  
72 Clarence Avenue  
Clapham Park  
London  
United Kingdom  
SW4 8JP

**Study participating centre**  
**Park Group Practice**  
Annerley  
London  
United Kingdom  
SE20 8AJ

**Study participating centre**  
**St Thomas' Hospital**  
Westminster Bridge Road  
London  
United Kingdom  
SE1 7EH

**Study participating centre**  
**University of Bristol**  
Room 1.01a  
Canynges Hall  
39 Whatley Road  
Bristol  
United Kingdom  
BS8 2PS

## **Sponsor information**

**Organisation**  
University of Nottingham (UK)

**Sponsor details**

Research Innovation Services  
Kings Meadow Campus  
Lenton Lane  
Nottingham  
England  
United Kingdom  
NG7 2NR

**Sponsor type**

University/education

**ROR**

<https://ror.org/01ee9ar58>

**Funder(s)****Funder type**

Government

**Funder Name**

Health Technology Assessment Programme

**Alternative Name(s)**

NIHR Health Technology Assessment Programme, HTA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Results and Publications****Publication and dissemination plan**

To be confirmed at a later date

**Intention to publish date****Individual participant data (IPD) sharing plan**

The participant-level data will be freely available but the trialists are still working on their in-house policy as to how this information will be available.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	21/07/2017		Yes	No
<a href="#">Results article</a>	results	21/03/2020	24/02/2020	Yes	No
<a href="#">Results article</a>	SWAT results	08/06/2020		Yes	No
<a href="#">Statistical Analysis Plan</a>	version 2.0	06/01/2022	17/06/2022	No	No
<a href="#">Protocol file</a>	version 7.0	26/02/2021	16/11/2022	No	No
<a href="#">Results article</a>	5-year results	19/10/2022	16/11/2022	Yes	No
<a href="#">Results article</a>	Prevalence and risk factors for milk allergy overdiagnosis in the BEEP trial cohort	20/06/2024	20/06/2024	Yes	No
<a href="#">Results article</a>	Emollient application	18/07/2024	19/07/2024	Yes	No