

# Feasibility study of Barrier Enhancement for Eczema Prevention

<b>Submission date</b> 08/01/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 26/02/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/01/2019	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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Nottingham  
United Kingdom  
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## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT01142999

**Protocol serial number**  
UK: 09DE005; USA: 6083

## Study information

**Scientific Title**

Feasibility study of Barrier Enhancement for Eczema Prevention: a multicentre, assessor-blinded, randomised controlled trial

## **Acronym**

The BEEP Study

## **Study objectives**

Enhancing the skin barrier from birth with emollients will prevent or delay the onset of eczema in high risk infants.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

1. UK: Nottingham Research Ethics Committee 1, 13/11/2009, ref: 09/H0407/43
2. USA: OHSU Research Integrity Office

## **Study design**

Multicentre assessor-blinded randomised controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Prevention

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

Prevention of eczema

## **Interventions**

UK site:

The intervention group will apply emollient to the infants entire skin surface once a day (except the scalp which is optional) especially after bathing. Parents will choose from three emollients that vary in texture and viscosity:

1. Sunflower seed oil
2. Doublebase
3. 50:50 white soft paraffin/liquid paraffin

The control group will not apply emollients

USA site:

The intervention group will apply emollient to the infants entire skin surface once a day (except the scalp which is optional) especially after bathing. Parents will choose from three emollients that vary in texture and viscosity:

1. Sunflower oil
2. Cetaphil cream
3. Aquaphor ointment

The control group will not apply emollients

Both sites:

The intervention will commence within 3 weeks of the birth. Both the intervention and control groups will receive best practice instructions on bathing and cleansing of their infant which will

be standardised to minimise investigator counselling and inter-investigator variability:

1. Avoid the use of soap and bubble bath
2. Use only a mild cleanser and shampoo
3. The use of baby wipes will be discouraged

Total duration of treatment and follow up is 6 months for all arms.

As of 21/03/2012, the record has been updated to include the following:

The study has been extended to follow up the participants until their 2nd birthday. The 6 month intervention period remains unchanged.

Sponsor details for the USA site:

National Eczema Association (USA)

4460 Redwood Highway, Suite 16-D

San Rafael, California

94903-1953

United States of America

Website: <http://www.nationaleczema.org>

Contact details for the USA site :

Dr Eric Simpson

Oregon Health & Science University

Department of Dermatology (CH16D)

3303 S.W. Bond Avenue

Portland, Oregon

97239-4501

United States of America

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Sunflower seed oil, Doublebase, white soft paraffin, liquid paraffin

### **Primary outcome(s)**

Proportion of families willing to be randomised. This is the most critical component of the success of any future trial.

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

1. Proportion of families eligible for the trial
2. Proportion of families accepting the initial invitation to participate
3. Proportion of families who found the interventions acceptable
4. Reported adherence with intervention
5. Proportion of families for whom the blinding of the assessor to the allocation status was not compromised
6. Amount of contamination as a result of increased awareness in the control group
7. Percentage of missing data and early withdrawal rates
8. Incidence of emollient-related adverse events

9. Incidence of eczema at 6 months
10. Age at onset of eczema and the proportion which are transient cases
11. Filaggrin mutation status

**Completion date**

01/02/2013

## Eligibility

**Key inclusion criteria**

UK and USA:

1. Infants with a family history of eczema, asthma or allergic rhinitis
2. Infant in overall good health
3. Mother aged between 16 and 45 years at delivery and capable of giving informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Sex**

All

**Key exclusion criteria**

UK and USA:

1. Preterm birth (defined as birth prior to 37 weeks gestation)
2. Major congenital anomaly
3. Hydrops fetalis
4. Significant dermatitis at birth not including seborrheic dermatitis (cradle cap) (added 13/07/2010)
5. Any severe genetic skin disorder or immunodeficiency
6. Any other serious condition that would make the use of emollients inadvisable
7. Any other major medical problems that the investigator deems may increase the risk of adverse events with the intervention or in whom assessing the outcomes may be masked by the underlying problem or practically very difficult to assess
8. Taken supplements containing Lactobacillus Rhamnosus during pregnancy or plan to take whilst lactating (added 13/07/2010)

**Date of first enrolment**

01/02/2010

**Date of final enrolment**

01/02/2013

## Locations

**Countries of recruitment**

United Kingdom

England

United States of America

**Study participating centre**

**Centre of Evidence Based Dermatology**

Nottingham

United Kingdom

NG7 2NR

## **Sponsor information**

**Organisation**

Nottingham University Hospitals NHS Trust (UK)

**ROR**

<https://ror.org/05y3qh794>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Programme Grants for Applied Research (PGfAR) (ref: RP-PG-0407-1017)

**Alternative Name(s)**

NIHR Programme Grants for Applied Research, PGfAR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

National Eczema Association (USA) (added 13/07/2010)

**Alternative Name(s)**

National Eczema Assoc., The National Eczema Association, NEA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Associations and societies (private and public)

**Location**

United States of America

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/10/2014		Yes	No
<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