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Feasibility study of Barrier Enhancement for Eczema Prevention

Submission date	Recruitment status
08/01/2010	No longer recruiting
Registration date	**Overall study status**
26/02/2010	Completed
Last Edited	**Condition category**
04/01/2019	Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.beepstudy.org

Contact information

Type(s)
Scientific

Contact name
Dr Joanne Chalmers

Contact details
Centre of Evidence Based Dermatology
Kings Meadow Campus
University of Nottingham
Lenton Lane
Nottingham
United Kingdom
NG7 2NR

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01142999

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Can be found at http://www.beepstudy.org

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

Secondary outcome measures
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

Overall study start date
01/02/2010

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

Age group
Child

Sex
Both

Target number of participants
200 infants to be enrolled

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
England

United Kingdom

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)

Sponsor details
Research & Development Department
E11, Curie Court
Queens Medical Centre
Nottingham
England
United Kingdom
NG7 2UH

Sponsor type
Hospital/treatment centre

Website
http://www.nuh.nhs.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., NEA

Funding Body Type
Government organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United States of America

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2014		Yes	No