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Barrier Enhancement for Eczema Prevention

Submission date
25/07/2014

Recruitment status
No longer recruiting

Registration date
25/07/2014

Overall study status
Completed

Last Edited
19/07/2024

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] 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
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Study website
http://beepstudy.org/

Contact information

Type(s)
Scientific

Contact name
Dr Laura Wyatt

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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 childs 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 childs 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 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 Diagnosic Criteria for atopic deramtitis; 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 ≥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
Canynge 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?
Protocol article	protocol	21/07/2017		Yes	No
Results article	results	21/03/2020	24/02/2020	Yes	No
Results article	SWAT results	08/06/2020		Yes	No
Statistical Analysis Plan	version 2.0	06/01/2022	17/06/2022	No	No
Protocol file	version 7.0	26/02/2021	16/11/2022	No	No
Results article	5-year results	19/10/2022	16/11/2022	Yes	No
Results article	Prevalence and risk factors for milk allergy overdiagnosis in the BEEP trial cohort	20/06/2024	20/06/2024	Yes	No
Results article	Emollient application	18/07/2024	19/07/2024	Yes	No