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Best emollients for eczema

Submission date	Recruitment status	[X] Prospectively registered
08/05/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/06/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/11/2023	Skin and Connective Tissue Diseases	

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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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.

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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

Study website
http://www.bristol.ac.uk/bee-study

Contact information

Type(s)
Public

Contact name
Ms Sian Wells

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Additional identifiers

EudraCT/CTIS number
2017-000688-34

IRAS number
214900

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
34197, IRAS 214900

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)
South West – Central Bristol Research Ethics Committee, 31/05/2017, ref: 17/SW/0089

Study design
Randomized; Interventional; Design type: Treatment, Drug

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Available on study website: www.bristol.ac.uk/bee-study/

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

Secondary outcome measures
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)

Overall study start date
01/05/2017

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

Age group
Child

Lower age limit
6 Months

Upper age limit
12 Years

Sex
Both

Target number of participants
Planned Sample Size: 520; UK Sample Size: 520

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
England

United Kingdom

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

Sponsor details
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College Green
One Cathedral Square
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+44 117 928 9827
research-governance@bristol.ac.uk

Sponsor type
University/education

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

Publication and dissemination plan
The trial will be publicised from the outset to academic and non-academic audiences including commissioners, clinicians, service providers and self-help groups (e.g. National Eczema Society).

In addition to our final monograph for the NIHR HTA Programme, the trial results will be published in peer-reviewed journals and presented at national and international meetings approximately one year after the trial ends. Opportunities for press releases and media interviews, and dissemination via Academic Health Science Network (AHSN) (Network of Networks), will also be sought.

Intention to publish date
01/09/2021

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?
Protocol article	protocol	06/11/2019	17/02/2021	Yes	No
Results article		23/05/2022	26/05/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Parent/Carer Consent Form and Assent Form for children version 3.0	03/11/2017	11/07/2023	No	Yes
Results article		01/10/2023	06/11/2023	Yes	No