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Choice Of Moisturiser in Eczema Treatment (COMET)

Submission date	Recruitment status
01/05/2014	No longer recruiting
Registration date	**Overall study status**
01/05/2014	Completed
Last Edited	**Condition category**
21/11/2016	Skin and Connective Tissue Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

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 General Practitioner (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. This is a problem because patients may have to make several appointments before they are given an emollient that works for them and it may be that older, cheaper emollients are as good as, or better, than newer, more expensive ones. We want to find out whether it is possible to conduct a large study that will answer the question 'What is the most clinically and cost effective primary emollient to use in infants with eczema?'.

Who can participate?
Parents/carers of 160 children with eczema who are younger than 3 years old can participate in this study.

What does the study involve?
Participants will be prescribed at random one of four widely available emollients (either a cream, a lotion, a gel or an ointment) to use regularly for 3 months. During this time carers will be asked to complete daily diaries about their child's symptoms and use of emollients and other treatments for eczema, and a researcher will assess the severity of eczema at monthly intervals.

What are the possible benefits and risks of participating?
At the end of this study we will have some useful information about the use of emollients and how to assess their effectiveness. We will also be able to decide if it is possible to conduct a larger study. Findings from this and the future study will improve the decision making around which emollient to prescribe first in infants with eczema.

Where is the study run from?
The study is being run by the University of Bristol, in collaboration with 16 GP practices throughout Bristol, North Somerset and South Gloucestershire, UK.

When is the study starting and how long is it expected to run for?
The study starts in June 2014 and runs until August 2015.

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Dr Victoria J Wilson
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Study website
http://www.bristol.ac.uk/comet

Contact information

Type(s)
Scientific

Contact name
Dr Victoria J Wilson

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Additional identifiers

EudraCT/CTIS number
2013-003001-26

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16571

Study information

Scientific Title
Choice Of Moisturiser in Eczema Treatment (COMET): a feasibility study for a pragmatic, single blind, randomised clinical trial to compare the clinical and cost effectiveness of leave-on emollients in treatment of infant eczema in primary care

Acronym
COMET

Study objectives
Can a study comparing the effectiveness of four different moisturisers used to treat children with eczema be done?

Ethics approval required
Old ethics approval format

Ethics approval(s)
13/SW/0297; First MREC approval date 19/11/2013

Study design
Feasibility study of a single-centre four-arm single-masked randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Children, Primary Care; Subtopic: All Diagnoses, Not Assigned; Disease: All Diseases, All Diseases

Interventions
The participants will be randomised to receive one of four commonly prescribed emollients (Diprobase® cream, Aveeno® lotion, Doublebase® gel or Hydromol® ointment), with directions to apply topically twice daily and throughout the day as required. They will be followed up every 28 days by the clinical studies officers, for 3 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Adherence and retention; Timepoint(s): 3 months

Secondary outcome measures
1. Blinding; Timepoint(s): 3 months
2. Data completeness; Timepoint(s): 3 months
3. EASI; Timepoint(s): Day 0, 28, 56 & 84
4. MCID of biophysical and objective eczema severity measures; Timepoint(s): 0, 1, 2 and 3 months
5. POEM; Timepoint(s): Weekly for 84 days
6. SASSAD; Timepoint(s): Day 0, 28, 56 & 84
7. TIS; Timepoint(s): Day 0, 28, 56 & 84

Overall study start date
01/06/2014

Completion date
31/08/2015

Eligibility

Key inclusion criteria
1. Children aged between 1 month and 3 years of age with doctor-diagnosed eczema
2. Adult with parental responsibility available to give consent
Target Gender: Male & Female; Upper Age Limit 3 years ; Lower Age Limit 1 months

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Months

Upper age limit
3 Years

Sex
Both

Target number of participants
Planned Sample Size: 160; UK Sample Size: 160

Key exclusion criteria
Child known to be sensitive or allergic to any of study emollients or their constituents

Date of first enrolment
01/06/2014

Date of final enrolment
31/08/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Academic Primary Care, School of Social and Community Medicine
Bristol
United Kingdom
BS8 2PS

Sponsor information

Organisation
University of Bristol (UK)

Sponsor details
Research & Enterprise Development (RED)
University of Bristol
Senate House
Tyndall Avenue
Bristol
England
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Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK); Grant Codes: PB-PG-0712-28056

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
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?
Protocol article	protocol	15/07/2015		Yes	No
Results article	results	16/11/2016		Yes	No
Results article	results	17/11/2016		Yes	No
HRA research summary			28/06/2023	No	No