

Choice Of Moisturiser in Eczema Treatment (COMET)

Submission date 01/05/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 01/05/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/11/2016	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> 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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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2013-003001-26

Protocol serial number
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

Study type(s)

Treatment

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(s)

Adherence and retention; Timepoint(s): 3 months

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

1 months

Upper age limit

3 years

Sex

All

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**

United Kingdom

England

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)

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

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

[Study website](#)

Study website

11/11/2025

11/11/2025

No

Yes