ISRCTN21828118 https://doi.org/10.1186/ISRCTN21828118

# 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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# Contact information

### Type(s)
Scientific

### Contact name
Dr Victoria J Wilson

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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 |

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|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |