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Bath Additives for the Treatment of Childhood Eczema

Submission date
09/12/2013

Recruitment status
No longer recruiting

Registration date
13/12/2013

Overall study status
Completed

Last Edited
26/11/2018

Condition category
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 skin condition that is very common in young children. It causes itching and sleep problems which lead to distress for the child and the rest of the family and can also impact on schooling and everyday tasks. The main treatment is emollients which moisturise the skin, and steroid creams/ointments to treat flare-ups caused by skin inflammation. A guideline on childhood eczema has recommended 'complete emollient therapy' - a care package that includes directly applied emollient, soap substitute emollient and bath emollient (a liquid added to the bath). However, the guideline highlighted that there is little research evidence on whether adding in a bath emollient is helpful.
While health professionals agree about the benefits of directly applied emollients and avoiding soap for children with eczema, there is less confidence in the possible additional benefits of bath emollients. It is possible that they do help because they are easy to pour in the bath and it is likely that they come into contact with all of the skin. However, it is also possible that the emollient effect is much less than the direct application of emollients onto the skin, and not enough to produce any benefit. Bath emollients can have adverse effects as they sometimes cause stinging and redness of the skin, potentially cause accidents through leaving the bath slippery, and may rot bath mats and lead to increased time spent cleaning the bath.
Furthermore, there is concern that some families view bath emollients as an alternative to directly applied emollients and are therefore using a less effective therapy instead of something that would help their child's eczema more. This study will measure whether bath emollients help children with eczema.

Who can participate?
Children aged 1 to 11 with mild eczema.

What does the study involve?
Children will be randomly allocated to one of two groups:
1. Standard eczema management with bath emollient
2. Standard eczema management without bath emollient
We will ask parents or carers to complete weekly diaries including a short questionnaire about eczema severity for the first 4 months, the time period during which the greatest effect is likely, and will check how many flare-ups of eczema are recorded in their GP records over 1 year. We

will also ask parents and carers about any side effects or difficulties they have using the treatment (adherence to treatment). We will also measure use of additional treatments, such as directly applied emollients, from the GP prescribing.

What are the possible benefits and risks of participating?
There is a lot of uncertainty amongst dermatologists, GPs and parents about whether or not bath emollients help children with eczema. By taking part in the study carers will help to answer this question, which will be useful for their child's eczema and for other families in the future. Bath emollients have been widely used for many years and there are no concerns about their safety, except that they can increase the risk of slipping in the bath and they sometimes cause skin irritation.

Where is the study run from?
This study is being run from the University of Southampton, Cardiff University and the University of Bristol. Southampton is the lead centre.

When is the study starting and how long is it expected to run for?
The recruitment is expected to start in November 2014. We will recruit for 18 months and each participant will be followed-up for 12 months.

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2013-004589-32

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 11/153/01, v1

Study information

Scientific Title
Bath Additives for the Treatment of Childhood Eczema: randomised controlled trial

Acronym
BATHE

Study objectives
This study aims to determine the clinical and cost-effectiveness of adding bath emollient to the standard management of atopic eczema in children.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/1115301

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Research Ethics Committee – approval pending

Study design
Pragmatic two-armed non-blinded 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
Childhood eczema

Interventions

Children will be randomised online to either regular bath emollients prescribed by the GP in addition to standard eczema care, or to standard eczema care without bath emollients.

The total duration of intervention is 12 months for both arms and the total duration of follow-up is 12 months for both arms.

Intervention Type
Other

Primary outcome measure
Weekly eczema severity measured by POEM (Patient-Oriented Eczema Measure) questionnaires weekly for 16 weeks.

Secondary outcome measures
1. Eczema severity over 1 year by administering POEM every 4 weeks from 16 weeks to 12 months.
2. Number of eczema exacerbations resulting in a primary healthcare consultation over 1 year. This will be assessed by a review of participants' primary care records at 1 year, and exacerbations will be defined as consultations where there is mention of eczema and topical steroid has been advised or prescribed.
3. Disease-specific QoL at baseline, 16 weeks and 1 year, measured by DFI (Dermatitis Family Impact), IDQoL (Infants Dermatitis Quality of Life index) and CDLQI (Childrens Dermatology Life Quality Index).
4. Generic QoL as measured by the Child Health Utility 9D (CHU 9D), a paediatric health related quality of life measure for use in economic evaluations, and the Health Utility Index II (HUI2), a utility measure that has been widely used in paediatric research (the UK valuation tariff will be used).
5. Type (strength) and quantity of topical steroid/calcineurin inhibitors prescribed, measured by GP record review at 12 months.

Overall study start date
01/11/2014

Completion date
01/03/2018

Eligibility

Key inclusion criteria
Children aged >1 and <12 years with atopic eczema

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
405

Key exclusion criteria
1. Children with inactive or very mild eczema (5 or less on Nottingham Eczema Severity Scale)
2. Children who usually have a bath less than once per week

Date of first enrolment
01/11/2014

Date of final enrolment
01/05/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The University of Southampton
Southampton
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SO16 5ST

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
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Sponsor type
University/education

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http://www.southampton.ac.uk/

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment (HTA) (UK) 11/153/01

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/05/2018

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	01/11/2015		Yes	No
Results article	results	03/05/2018		Yes	No
Results article	results	01/10/2018		Yes	No
Results article	results	24/10/2018		Yes	No