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Children with eczema, antibiotic management study

Submission date
20/06/2012

Recruitment status
No longer recruiting

Registration date
27/06/2012

Overall study status
Completed

Last Edited
24/07/2019

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Eczema is a common, debilitating skin condition in children that causes dryness and itching. Everyone naturally has bacteria on their skin, though one called Staphylococcus aureus is more frequently found on the skin of children with eczema. These bacteria may make the eczema worse. However, studies of treatments designed to eliminate or reduce Staphylococcus aureus have been unclear. It is unknown whether children consulting a general practitioner with eczema which is suspected to be infected will benefit from antibiotic treatment. Furthermore, we do not know if taking an antibiotic by mouth or using an antibiotic cream on the skin is better. The aim of this study is to answer the following question: does the addition of oral or topical antibiotic treatment to treatment with corticosteroid cream, reduce eczema severity in children with infected eczema in primary care?

Who can participate?
Children aged 3 months to less than 8 years with suspected infected atopic eczema.

What does the study involve?
Children suitable for the study are identified by doctors (General Practitioners). If the child's parent/carer agrees, children are randomly put into one of three treatment groups (for one week): oral antibiotic and placebo (dummy) cream; oral placebo and antibiotic cream; oral placebo and placebo cream. Children taking part are followed-up over 12 months. A trained research nurse visits each child during the first 4 weeks and uses questionnaires to assess the severity of eczema, quality of life, healthcare consultations and impact on the family, and take swabs from the skin, nose and mouth. The child's parent/carer is asked to complete a diary during the first 4 weeks to record symptom severity and use of medication. After 3 and 12 months the parent/carer is asked to complete questionnaires and repeat the swabs. These swabs are used to assess the impact of treatments on bacterial resistance; to determine the relationship between antibiotic use and subsequent development of antibiotic resistance; and to measure the antibiotic sensitivity of bacteria found on the skin, nose and mouth.

What are the possible benefits and risks of participating?
The participant and their parent/carer(s) will receive additional advice and support from the study nurse about caring for eczema and using standard eczema treatments (emollient

moisturisers and steroid creams). The nurse will also monitor the participating child's health over the first four weeks. In addition, the parent/carer(s) will be helping us answer questions about the treatment of eczema in children that should result in better care for children with eczema in the future. As a token of appreciation for their time spent participating in the study, we will give participants a total of £20 in gift vouchers during the study (£10 at the start of the study, £5 at 3 months and £5 at 12 months). Taking part in the study will mean that participants and their parent/carer(s) will give up some of their time. There is a chance that the participating child might develop side effects from the study medication. However, the antibiotics used in this study are the same types of antibiotics GPs prescribe every day to treat infected eczema, and the risk of side effects will be no greater than normal. Side effects are uncommon with these medications, and are not usually serious. More details of the study medication will be provided at the time the research nurse shows the parent/carer(s) how to give their child their medication. Whether or not eligible children enter this study, there is a chance that their eczema may get better or worse.

Where is the study run from?
The CREAM study will be lead by the South East Wales Trials Unit, Cardiff University in collaboration with the University of Dundee and University of Bristol.

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start autumn 2012. It is hoped each participant will be enrolled on the study for 12 month from recruitment; however, the study will run for a total of 3 years.

Who is funding the study?
Health Technology Assessment Programme (HTA) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 09/118/03, v1.1

Study information

Scientific Title
The CREAM Study: ChildRen with Eczema, Antibiotic Management Study: a randomised controlled trial

Acronym
CREAM

Study objectives
Does the addition of oral or topical antibiotic treatment to treatment with corticosteroid cream reduce subjective eczema severity in children with suspected infected eczema in primary care?

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/0911803
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0017/81602/PRO-09-118-03.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
REC for Wales Ref:12/WA/0180

Study design
Three-arm randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Infected eczema

Interventions
The active medications being evaluated in this trial are well established and already widely used within their licensed indications. The active medications will not be used outside their licensed indication in the course of this trial. This is a study of their added value.

The trial has three treatment arms. Participants in all three treatment arms will receive a suitable standard topical corticosteroid treatment for their eczema and comprehensive verbal and written eczema care instructions. All participants will also receive additional monitoring and support of a trained research nurse.

Group 1: Oral antibiotic flucloxacillin (or erythromycin if penicillin allergic) and topical placebo.
Group 2: Oral placebo and topical antibiotic fusidic acid 2% cream.
Group 3: Oral placebo and topical placebo

Groups 1, 2 and 3:
All patients will be prescribed topical steroid cream [topical Eumovate cream (for eczema on trunk and/or limbs) and/or topical hydrocortisone 1% cream (for eczema on face)] by their GP.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Flucloxacillin, erythromycin, fusidic acid

Primary outcome(s)
Assessment of subjective severity at two weeks as measured using the validated Patient-Oriented Eczema Measure (POEM). The POEM is based on symptoms over the previous week and therefore will be measuring symptom severity during the week following the end of experimental treatment, the period when a treatment effect is most likely. We have chosen a subjective measure for our primary outcome in recognition of the importance of measuring effects that are of importance to patients. The POEM has been found to be valid and reliable, easy to complete, sensitive to change, and was one of three outcome measures recommended in a recent systematic review of outcome measures for atopic eczema (AE).

Key secondary outcome(s))
1. Subjective eczema severity will be measured using the Eczema Area and Severity Index (EASI). This was also recommended as an eczema outcome measure, and was selected over SCORAD because it includes assessments of each of four body areas and therefore may be of value in assessing response within the infected region. In addition, the SCORAD combines subjective and objective assessments.
2. Quality of life will be assessed using the Infants Dermatology Quality of Life instrument (IDQoL)
3. Impact on the family will me measured using the Dermatitis Family Impact (DFI) instrument. These are both well-validated, short, easy to use instruments, and we have expertise in our team in using them. The IDQoL is intended for children up to 4 years of age. However, it has been successfulLY used in studies with children up to 5.
4. A four question condition-specific, preference-based measure of health for children will be used for the exploratory cost utility analysis.
5. A daily diary will be used to record symptom severity, medication use, carers preference for treatment (recorded at 2 weeks), and healthcare use during the first 4 weeks. The diary will record the following symptoms each day: carers assessment of overall severity, itch, sleep disturbance, oozing or weeping, bleeding, fever, and possible adverse effects (nausea, vomiting, diarrhoea, abdominal pain, joint pains, new rash). We will pilot this diary with a sample of carers prior to use in the trial. We have had success in using daily symptom diaries in a number of studies, including four-week diaries, and diaries completed by parents/carers. One study successfully collected daily diary data from the majority of parents/carers for eight weeks. There is also evidence for the reliability and validity of diary data recorded by parents/carers.

Completion date
25/03/2015

Eligibility

Key inclusion criteria
Children (aged 3 months to less than five years) with atopic eczema (as defined by UK working party criteria) who are presenting in primary care and their treating clinician suspects infected eczema because of at least one of the following:
The UK working party criteria state that in order to qualify as a case of atopic eczema with the UK diagnostic criteria, the child MUST have:
1. An itch skin condition in the last 12 months
2. And three or more of the following:
2.1. Onset below age 2 (Not used in children under 4 years old)
2.2.History of flexural involvement.
2.3. History of general dry skin atopic disease (In children aged under 4 years old, history of atopic disease in a first degree relative may be included)
2.4. Personal history of other atopic disease
3. The eczema is failing to respond to standard treatment
4. There is a flare in the severity or extent of the eczema
5. There is weeping, crusting, or pustules

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 months

Upper age limit
5 years

Sex
All

Key exclusion criteria
1. Use of oral or topical antibiotics in the past week
2. Use of potent (Betamethasone valerate 0.1%, Betacap, Betesil, Bettamousse, Betnovate, Cutivate, Diprosone, Elocon, Hydrocortisone butyrate, Locoid, Locoid Crelo, Metosyn, Nerisone, Synalar, Aureocort, Betnovate-C, Betnovate-N, Fucibet, Lotriderm, Synalar C, Synalar N, Diprosalic) or very potent (Clarelux, Dermovate, Etrivex, Nerisone Forte, Dermovate-NN) corticosteroids within the past week
3. Immune suppression
4. Features suggestive of eczema herpeticum (significant pain, punched out lesions)
5. Severe infection (systemic upset, cellulitis)) and/or suspected infection warrants immediate

hospitalisation or urgent dermatology referral
6. Severity of eczema
7. Known renal and / or hepatic impairment
8. Allergy to penicillin and erythromycin or allergy to penicillin and contraindication to erythromycin, such as current use of medication that is known to interact with erythromycin
9. Allergy the fusidic acid
10. Current use of any medication that is known to interact with fuscidic acid
11. Extensive eczema (EASI score 40 [equates to moderately severe eczema affecting 80% of body surface area])

Date of first enrolment
01/09/2012

Date of final enrolment
28/11/2014

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff University
Cardiff
United Kingdom
CF14 4YS

Sponsor information

Organisation
Cardiff University (UK)

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

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
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016		Yes	No
HRA research summary			28/06/2023	No	No
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