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CLOTHES Trial: Clothing for the relief of eczema symptoms

Submission date
11/10/2013

Recruitment status
No longer recruiting

Registration date
11/10/2013

Overall study status
Completed

Last Edited
25/01/2019

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 condition that causes the skin to become itchy, red, dry and cracked. Specialist silk clothing has been promoted recently as a new treatment option for people with eczema, but it is unclear if these garments really do provide additional benefits for patients. Research is needed to find out whether or not these new products live up to the impressive claims that are currently being made. As a result, we are about to conduct a study of silk clothing for the management of eczema in children.

Who can participate?
Children between 1 and 15 years of age who have quite bad eczema.

What does the study involve?
Each child will be enrolled in the study for 8 months in total, and will be asked to attend their local recruiting hospital on four different occasions. Children participating in the study will be put into one of two groups. The first group will receive three sets of silk underwear – this will be either a bodysuit and leggings, or vest and leggings depending on the child's age. The children will be asked to wear the clothing underneath their normal clothes day and night for six months - if possible! The second group will not receive the clothing straight away but will be given the clothing to try for themselves after the first 6 months of the study has finished. Throughout the study all of the children will be free to continue with their usual eczema treatments, such as emollients and topical steroids, and will be asked to complete a weekly questionnaire at home so that they can tell us how the eczema has been, and how often the clothing has been worn.

What are the possible benefits and risks of participating?
If we can show that these clothes provide additional benefits for patients, then this would be an important finding, and many eczema sufferers could benefit. Equally, if the research shows that the clothes provide no useful benefit, then patients and the NHS can save money by not using treatments that have been shown to be ineffective.

Where is the study run from?
Recruitment is taking place in hospitals in five main areas – Nottingham, Cambridge, north London, Portsmouth and the Isle of Wight. This study is being led from the Centre of Evidence

Based Dermatology at the University of Nottingham, and will be co-ordinated from the Nottingham Clinical Trials Unit.

When is the study starting and how long is it expected to run for?
Recruitment is due to start in November 2013 and will continue for about 18 months.

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

Who is the main contact?
Professor Kim Thomas
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
15132; HTA 11/65/01

Study information

Scientific Title
Randomised controlled trial of silk therapeutic CLOTHing for the long-term management of Eczema Symptoms in children

Acronym
CLOTHES

Study objectives
The purpose of this study is to establish whether silk therapeutic clothing is effective in the long-term management of eczema in children.

Primary Objective
To assess whether silk therapeutic clothing, when used in addition to standard eczema care, reduces eczema severity in children over a period of six months.

Secondary Objective
To estimate the within trial cost-effectiveness of silk therapeutic clothing with standard care, compared to standard care alone, from an NHS and a family perspective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham 1, First MREC approval date 16/07/2013, ref: 13/EM/0255

Study design
Randomised interventional treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England, Skin, Generic Health Relevance and Cross Cutting Themes; Subtopic: Not Assigned, Skin (all Subtopics), Generic Health Relevance (all Subtopics); Disease: Dermatology, All Diseases, Paediatrics

Interventions
Children will be randomised into one of two groups - standard care plus silk clothing, or standard care only (for the 6-month RCT period). Participants allocated to standard care will receive the clothing after the 6-month clinic visit, and both groups will be followed up for a further 2 months by questionnaire.

Silk therapeutic clothing, The medical device under investigation is a knitted, sericin-free silk therapeutic garment with a CE mark for use in eczema.

For both arms: duration of treatment is 6 months, duration of follow-up is 8 months

Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Phase IV

Primary outcome(s)
Eczema severity measured by the objective Eczema Area and Severity Index (EASI); Timepoint(s): Baseline, 2 months, 4 months, 6 months

Key secondary outcome(s))
1. Global assessment of the eczema by research nurses (IGA) and by participants (PGA); Timepoint(s): Baseline, 2 months, 4 months, 6 months
2. Three Item Severity scale (TIS) used to assess eczema severity; Timepoint(s): Baseline, 2 months, 4 months and 6 months
3. Use of topical treatments; Timepoint(s): Throughout the trial
4. Self reported eczema symptoms using the Patient Oriented Eczema measure (POEM); Timepoint(s): Weekly throughout the trial
5. Health Related Quality of Life (DFI, EQ-5D-3L, ADQoL, CHU-9D); Timepoint(s): Baseline and 6 months
6. Durability of garments and acceptability of use.; Timepoint(s): 6 months and 8 months, and adherence; Timepoints: Throughout the trial
7. Cost-effectiveness and cost utility; Timepoint(s): 6 months

Completion date
02/05/2016

Eligibility

Key inclusion criteria
1. Children aged 1 to 15 years at baseline
2. Diagnosis of moderate or severe eczema (atopic dermatitis). Presence of eczema will be confirmed using the UK. Diagnostic Criteria for Atopic Eczema and eczema severity judged using the Nottingham Eczema Severity Scale (NESS)
3. Resident within travelling distance of a recruiting centre
4. Children with at least one patch of eczema on the trunk or limbs
5. Parent/legal guardian able to give informed consent
6. Target Gender: Male & Female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1 years

Upper age limit
15 years

Sex
All

Key exclusion criteria
1. Children who have taken systemic medication (including light therapy) or oral steroids for eczema within the previous three months

2. Children who have started a new treatment regimen within the last month
3. Children who have used wet/dry wraps ≥5 times in the last month
4. Children who are currently using silk clothing for their eczema and are unwilling to stop using the clothing during the trial
5. Children who are currently taking part in another clinical trial
6. Children who have expressed a wish not to take part in the trial

Date of first enrolment
01/11/2013

Date of final enrolment
01/05/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Nottingham
Nottingham
United Kingdom
NG7 2NR

Sponsor information

Organisation
University of Nottingham (UK)

ROR
https://ror.org/01ee9ar58

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
The study used identifiable individual patient data which is subject to ethics, consent and privacy restrictions. However within these constraints, the trialists will make fully anonymised data available on request wherever possible, e.g. for individual patient data meta-analysis. Applications for data access should be made via the CLOTHES Data Access Committee (contact sponsor@nottingham.ac.uk ref: RC3215, and copy in the Chief Investigator kim.thomas@nottingham.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2017		Yes	No
Results article	results	11/04/2017		Yes	No
Protocol article	protocol	02/09/2015		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