

CLOTHES Trial: Clothing for the relief of eczema symptoms

Submission date 11/10/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/10/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/01/2019	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 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
Kim.Thomas@nottingham.ac.uk

Study website
<http://www.nottingham.ac.uk/clothes>

Contact information

Type(s)
Scientific

Contact name
Prof Kim Thomas

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Patient information sheets can be found at www.nottingham.ac.uk/clothes

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 measure

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

Secondary outcome measures

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

Overall study start date

01/11/2013

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

Age group

Child

Lower age limit

1 Years

Upper age limit

15 Years

Sex

Both

Target number of participants

UK Sample Size: 300; Description: 150 allocated to standard eczema care + silk clothing (active), 150 allocated to standard care (control)

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**

England

United Kingdom

Study participating centre

University of Nottingham

Nottingham

United Kingdom

NG7 2NR

Sponsor information

Organisation

University of Nottingham (UK)

Sponsor details

Research Innovation Services

Kings Meadow Campus

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abc@email.com

Sponsor type

University/education

Website

<http://www.nottingham.ac.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, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	02/09/2015		Yes	No
Results article	results	01/04/2017		Yes	No
Results article	results	11/04/2017		Yes	No
HRA research summary			28/06/2023	No	No