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Multi-centre randomised controlled trial of ion-exchange water softeners for the treatment of atopic eczema in children (Softened Water Eczema Trial)

Submission date
08/01/2007

Recruitment status
No longer recruiting

Registration date
17/01/2007

Overall study status
Completed

Last Edited
07/07/2011

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol
http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=89

Study website
http://www.swet-trial.co.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 05/16/01

Study information

Scientific Title

Acronym
SWET

Study objectives
A single-blind, parallel group randomised controlled trial of 12-week duration, followed by a 4-week cross-over period. Participants will be randomised to Arm A (usual eczema care + water softener for 12 weeks followed by 4 weeks with unit removed) or Arm B (usual eczema care for 12 weeks followed by delayed installation for the final 4 weeks of the study period).
Ion-exchange water softening units will be compared with usual eczema care. Ion exchange water softening is a scientifically defined, understood and described process using a synthetic polystyrene resin in which primarily the divalent cations (positively charged), calcium and magnesium found in domestic water supplies, are replaced by the monovalent cation, sodium, from common salt. Ion-exchange water softening units typically reduce the water hardness to practically zero .
All units will be installed in the childs principal residence and salt will be supplied for the duration of the trial. Standard procedure will be to soften all water in the home, and provide mains drinking water through an extra (faucet-style) tap installed at the side of the kitchen sink. Apart from having a unit installed in the home, participants will continue with their usual eczema treatments in the usual way and will be asked to bathe / wash their clothes according to their usual practice. The units will meet all necessary quality standards, and will be installed by a trained water engineer according to British Waters code of practice.
The water softeners to be used in this trial will be supplied and paid for by a consortium of representatives from the water softener industry, co-ordinated through their Trade Association (UK Water Treatment Association). The units will be encased in an unmarked box in order to prevent the possibility of commercial advantage to any particular company.

Hypotheses:
1. The installation of an ion-exchange water softener will help to relieve the symptoms of eczema in children with moderate to severe eczema
2. The installation of an ion-exchange water softener will result in cost implications to both patients and the NHS.

There is epidemiological evidence linking increasing water hardness with increasing atopic eczema prevalence. This was first demonstrated by the current research team in an ecological study published in The Lancet of 4141 randomly selected primary school children in the Nottingham area (McNally et al, 1998). The 1-year period prevalence of eczema was 17.3% in the hardest water category and 12.0% in the lowest (odds ratio of 1.54, 1.19-1.99 after adjustment for confounders). Similar results have recently been found in Japan (Miyake et al, 2004).

If the above associations are true, a number of plausible mechanisms can be forwarded to suggest why hard water could exacerbate eczema. Perhaps the most likely explanation is increased soap usage in hard water areas; the deposits of which can cause skin irritation in eczema sufferers. A direct chemical irritant effect from calcium and magnesium salts is also possible, or an indirect effect of enhanced allergen penetration from skin barrier disruption.

McNally NJ, Williams HC, Phillips DR et al. Atopic eczema and domestic water hardness. Lancet 1998;352:527-531

Miyake Y, Yokoyama T, Yura A, Shimizu T. Ecological association of water hardness with prevalence of childhood atopic dermatitis in a Japanese urban area. Environmental Research 94 (2004) 33-37

Please note that as of 14/01/10 this trial has been updated. All updates can be found in the relevant field with the above update date.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West Multi-Centre Research Ethics Committee on 16/01/2007

Study design
Single blind parallel group randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: http://www.swet-trial.co.uk

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

Interventions
Ion-exchange water softener installed for 4 or 12 weeks. The research nurse is blinded as to intervention status.

Intervention Type
Other

Phase

Not Specified

Primary outcome measure

Difference between the active vs. standard treatment groups with regard to mean change in disease severity (SASSAD 5) at 12 weeks compared to baseline. SASSAD is an objective severity scale that is completed by the research nurse during follow-up appointments. It does not involve input from the patient in any way.

Secondary outcome measures

Current information as of 14/01/10:
1. Difference between the groups in the proportion of time spent moving during the night . Movement will be captured for periods of one week at week 1 and week 12 and will be measured using accelerometers (Actiwatch™). These units are worn by the child in the same way as a wrist watch. This outcome has been included as an objective surrogate for sleep loss and itchiness (two of the defining features of eczema). Previous research has suggested that this is a suitable objective tool for assessing itch and further pilot work is currently underway to assess its suitability for use within this trial.
2. Difference in those who report a reasonable (≤20%), good (>20% and ≤50%) or excellent (>50%) improvement in SASSAD score at 12 weeks.
3. Difference in Patient Oriented Eczema Measure (POEM) collected at baseline, weeks 4, 12 and 16. This scale is a well validated tool that has been developed to capture symptoms of importance to patients (rather than objective signs that are used in traditional severity scales, such as SASSAD).
4. Difference in the number of totally controlled weeks (TCW) and well controlled weeks (WCW) based on the number of days with eczema symptoms and the number of days that topical treatment is applied, up to the primary endpoint at 12 weeks. This outcome is based on a recent systematic review conducted by the applicants looking at ways of assessing long-term control for chronic conditions such as atopic eczema, asthma and rheumatoid arthritis. The terms TCW and WCW have been adopted for use by researchers in the field of asthma and appear to be a useful and intuitive means of capturing disease activity over time.
5. Difference in the mean change in the Dermatitis Family Impact (DFI) questionnaire at 12 weeks. This scale was chosen as an appropriate quality of life scale for the study for two reasons:
a. The intervention involves the entire household, so a quality of life scale appropriate to the family unit seems most appropriate
b. It avoids the need to use two different age-specific dermatology quality of life scales (the Childrens Dermatology Life Quality Index and the Infants version of the same scale)
6. Mean change in health related Quality of Life at 12 weeks. This will be captured using a generic measure of health utility (the childrens version of the EQ-5D for children aged 7 years and over, or the proxy version of the EQ-5D for children aged 3 to 6 years.
7. Difference in the amount of topical corticosteroid / calcineurin inhibitors used up to the primary endpoint at 12 weeks.

Initial information at time of registration:
1. Difference between the groups in the proportion of time spent moving during the night . Movement will be captured for periods of one week at week 1 and week 12 and will be measured using accelerometers (Actiwatch™). These units are worn by the child in the same way as a wrist watch. This outcome has been included as an objective surrogate for sleep loss and itchiness (two of the defining features of eczema). Previous research has suggested that this is a suitable objective tool for assessing itch and further pilot work is currently underway to assess its suitability for use within this trial.
2. Difference in proportion of children who report either good or excellent improvement in

eczema severity at 12 weeks (using a 5-point Likert scale).
3. Difference in Patient Oriented Eczema Measure (POEM) collected at baseline, weeks 4, 12 and 16. This scale is a well validated tool that has been developed to capture symptoms of importance to patients (rather than objective signs that are used in traditional severity scales, such as SASSAD).
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Overall study start date
01/09/2006

Completion date
31/08/2009

Eligibility

Key inclusion criteria
1. Children aged 6 months to 16 years at baseline, with eczema as defined by the UK refinement of the Hanifin and Rajka diagnostic criteria 14.
2. Eczema present at time of assessment (minimum Six Area Six Sign Atopic Dermatitis [SASSAD] score of 10).
3. Baseline water hardness of >200 mg/l of calcium carbonate.
4. Home suitable for the installation of a water softening device (as assessed by water engineer)
5. Property not > 5 storeys high

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
16 Years

Sex
Both

Target number of participants
310

Key exclusion criteria
1. Children who plan to be away from home for >21 days in total during the 16-week study period. This has been deemed necessary in order to ensure adequate exposure to the intervention. We will also aim to ensure children do not have a planned holiday in the 4 weeks prior to their 12 week assessment visit.
2. Children who have taken systemic medication (e.g. Cyclosporin A, methotrexate) or UV light for their eczema within the last 3 months because of their long lasting effects.
3. Children who have taken oral steroids within the last 4 weeks, or who, as a result of seeing a healthcare professional, have started a new treatment regimen for eczema within the last 4 weeks.
4. Families who already have a water treatment device installed, including ion-exchange softeners, polyphosphate dosing units or physical conditioners.

Date of first enrolment
01/09/2006

Date of final enrolment
31/08/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre of Evidence Based Dermatology
Nottingham
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Sponsor information

Organisation
University of Nottingham (UK)

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Sponsor type
University/education

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	01/09/2008		Yes	No
Results article	results	01/02/2011		Yes	No
Results article	results	15/02/2011		Yes	No