ISRCTN43865436 https://doi.org/10.1186/ISRCTN43865436

A trial of topical sodium cromoglicate in atopic dermatitis in children

Submission date	Recruitment status
14/09/2005	No longer recruiting
Registration date	**Overall study status**
12/10/2005	Completed
Last Edited	**Condition category**
14/08/2008	Skin and Connective Tissue Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
T&R.SkinP.01

Study information

Scientific Title

Acronym
T&R.SkinP.01

Study objectives
Sodium cromoglicate lotion applied topically to the skin is more effective than the vehicle in the treatment of atopic dermatitis in children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
Parallel group comparative randomised controlled trial:
1. 4% sodium cromoglicate in an aqueous lotion
2. The aqueous lotion vehicle

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The change in the SCORAD assessment score between end of baseline and after 12 weeks treatment.

Secondary outcome measures
1. The change in overall skin condition, itch and sleep disturbance recorded on the daily diary cards
2. The change in topical corticosteroid and/or immunomodulator drug use as recorded on the daily diary cards and by weighing of the tubes
3. The global assessments recorded at the end of the study by the parent and investigator
4. The change in Childrens Dermatology Life Quality Index (CDLQI) or Infant Life Quality Index

Overall study start date
01/10/2005

Completion date
30/06/2007

Eligibility

Key inclusion criteria
1. Children of either sex aged between 1 and 12 years (after the first birthday and before the 13th birthday)
2. Children with atopic dermatitis according to the UK Working Party for diagnostic criteria for atopic dermatitis. These are:
2.1. Must have an itchy skin condition (or report of scratching or rubbing in a child)
2.2. Plus three or more of the following:
2.2.1. History of itchiness in skin creases such as folds of the elbows, behind the knees, fronts of ankles, or around the neck (or the cheeks in children less than 4 years)
2.2.2. History of asthma or hay fever (or history of atopic disease in a first degree relative in children under 4 years)
2.2.3. General dry skin in the past year
2.2.4. Visible flexural eczema (or eczema affecting the cheeks or forehead and outer limbs in children under 4 years)
2.2.5. Onset in the first two years of life
3. Children with atopic dermatitis who at the Screening Visit (Visit 1) and at Visit 2 exhibit a score using the SCORing Atopic Dermatitis (SCORAD) scoring system for atopic dermatitis of greater than or equal to 25
4. Children of parents, one of whom gives signed, informed consent to participate in the trial

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
174

Key exclusion criteria
1. Children with any chronic disease other than associated allergic diseases (which include recurrent wheezing, allergic rhinitis and food allergy)
2. Children who have cardiovascular, neurological, hepatic, renal, gastrointestinal, or other significant acute or chronic medical indication which, in the judgement of the investigator, might interfere with the study or require treatment
3. Patients who have received oral corticosteroids or corticosteroids by injection within the past 3 months

Date of first enrolment
01/10/2005

Date of final enrolment
30/06/2007

Locations

Countries of recruitment
Norway

United Kingdom

Study participating centre
Voksentoppen BKL
Oslo
Norway
NO 0791

Sponsor information

Organisation
Thornton and Ross Ltd (UK)

Sponsor details
Stephen J Skilleter
Thornton & Ross Ltd
Linthwaite
Huddersfield
United Kingdom
HD7 5QH

Sponsor type

Industry

Website
http://www.thorntonross.com

ROR
https://ror.org/00frd0c49

Funder(s)

Funder type
Industry

Funder Name
Thornton and Ross Ltd (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?
Results article	Results	01/02/2005		Yes	No