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

A trial of topical sodium cromoglicate in atopic dermatitis in children

Submission date	Recruitment status	[_] Prospectively registered
14/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/10/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/08/2008	Skin and Connective Tissue Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Kai-Håkon Carlsen

Contact details
Voksentoppen BKL
National Hospital (Rikshoapitalet)
Ullveien14
Oslo
Norway
NO 0791

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
The change in the SCORAD assessment score between end of baseline and after 12 weeks treatment.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1 years

Upper age limit
12 years

Sex
All

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
United Kingdom

Norway

Study participating centre
Voksentoppen BKL
Oslo
Norway
NO 0791

Sponsor information

Organisation
Thornton and Ross Ltd (UK)

ROR
https://ror.org/00frd0c49

Funder(s)

Funder type
Industry

Funder Name
Thornton and Ross Ltd (UK)

Results and Publications

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