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A randomised controlled single-blind multi-centre study to investigate the induction of ALUminium contact allergy in children/adults receiving hyposensitisation therapy due to allergic disease

Submission date 25/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/02/2008	**Overall study status** Completed	
Last Edited 20/10/2009	**Condition category** Skin and Connective Tissue Diseases	

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
N/A

Study information

Scientific Title

Acronym
ALU study

Study objectives
The development of persisting itching nodules at the injection site after desensitisation therapy with aluminium precipitated antigen extract has been described in several reports, and also after vaccination with aluminium adsorbed vaccines.

The overriding aim of the planned study is to investigate the proportion of children and adults who develop contact allergy to aluminium during hyposensitisation therapy and if development of allergy to aluminium is linked to a persistent itching subcutaneous nodule.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local ethics committee (Regionala Etikprövningsnämnden i Lund, Avd 2) (ref: Dnr 277/2007)

Study design
Randomised, controlled, single-blind, multi-centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Allergy

Interventions
Intervention arm: Hyposensitisation therapy with aluminium precipitated antigen extract, used subcutaneously. The duration of hyposensitisation therapy varies between patients, as each patient receives a different course of treatment, depending on his/her condition.
Control arm: No treatment

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. To estimate the proportion of children and adults who develop contact allergy to aluminium during the hyposensitisation therapy measured by patch testing
2. To compare the proportion of children and adults with positive patch test reactions to aluminum between groups, those with persistent nodules with or without itching and those without manifestations/symptoms

All patch testing will be performed in close connection with the injections, which means on the same day or the following days. The patch test reader will be blinded - he/she will not know which patient has already received the hyposensitisation therapy and which has not (and will be receiving).

Secondary outcome measures
1. To investigate the frequency of contact allergy in atopic children (contact allergy to aluminium and other sensitizers present in the European Patch Test Series)
2. To compare the contact allergy rated between atopic children and adults with and without atopic dermatitis (contact allergy to aluminium and other sensitisers present in the European Patch Test Series)
3. To make comparison between groups considering the following possible risk factors for developing persisting itching nodules with contact allergy to aluminium:
3.1. Doses
3.2. Sex
3.3. Age
3.4. Other medication/exposure

Overall study start date
27/08/2007

Completion date
01/03/2009

Eligibility

Key inclusion criteria
1. Children and adults who will start their hyposensitisation therapy during 2007 and 2008
2. Written informed consent

Participant type(s)

Patient

Age group
Other

Sex
Both

Target number of participants
500

Key exclusion criteria
Experienced anaphylaxis during skin tests.

Date of first enrolment
27/08/2007

Date of final enrolment
01/03/2009

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Occupational and Environmental Dermatology
Malmö
Sweden
205 02

Sponsor information

Organisation
Malmö University Hospital (Sweden)

Sponsor details
Department of Occupational and Environmental Dermatology
Malmö
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205 02

Sponsor type
University/education

Website
http://www.hand.mas.lu.se

ROR
https://ror.org/05wp7an13

Funder(s)

Funder type
University/education

Funder Name
Department of Occupational and Environmental Dermatology, Malmö University Hospital, Malmö (Sweden)

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