

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	<input type="checkbox"/> Prospectively registered
Registration date 08/02/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/10/2009	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Not Specified

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(s)

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).

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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)

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

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration