

# 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

<b>Submission date</b> 25/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 08/02/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 20/10/2009	<b>Condition category</b> Skin and Connective Tissue Diseases	<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

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

Sweden

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