SubCutaneous Immunotherapy Treatment Effect (CITE) study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Observational invasive

Summary

ID

NL-OMON36931

Source
ToetsingOnline

Brief title
CITE study

Condition

- Allergic conditions

Synonym
allergic rhinitis, hayfever

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Dept Pathophysiology and Allergy research;Medical University Vienna

Intervention

Keyword: birch pollen allergy, house dust mite allergy, specific immunotherapy, T-cells

Outcome measures

Primary outcome

For inhalant allergy (BP or HM): SIT-responsiveness will be defined by nasal responsiveness to BP or HM before and after 2 years of treatment. Participants will be divided in SIT-responders and non-responders according to the outcome of nasal challenge tests.

For birch pollen-associated food allergy: Responsiveness to BP-SIT as defined by oral challenge tests to Mal d 1 - the major allergen in apple * before and after 2 years of treatment. Participants will be divided in BP-SIT responders and non-responders according to the outcome of oral challenge tests.

Secondary outcome

For BP or HM allergy:

Additional study parameters to evaluate the effects of immunotherapy are changes in i) nasal responsiveness after 1 year, ii) immediate skin reactivity after one and two years, respectively, and iii) assessment of global scores on the symptoms of allergic rhinitis after one and two years

For BP allergy and apple sensitization:

Additional study parameters are changes in i) responsiveness to open apple challenges, after one and two years of BP-SIT ii) responsiveness to oral challenge with Mal d 1 after 12 months iii)immediate skin reactivity to birch pollen-associated food allergens (i.e. apple, peach and hazelnut) after one and

two years of BP-SIT.

Study description

Background summary

Allergen-specific immunotherapy (SIT) is the only causative treatment for IgE-mediated allergy. Successful SIT has been associated with the induction of allergen-specific *blocking* antibodies, regulatory T-cells and the shift from allergen-specific Th2 towards Th0/1-like responses. However, it is still not clear which of these immune mechanisms actually translate into clinical tolerance to allergens and why SIT is not successful in a substantial fraction of patients.

Study objective

We seek to elucidate the immune mechanism(s) that are relevant for clinical tolerance to inhalant and food allergens. For this purpose, patients suffering from allergy to birch pollen and/or house dust mite who receive routine-SIT will be assessed for the success of the treatment by employing nasal challenge tests with the respective allergens. In birch pollen-allergic patients, (changes in) tolerance and non-tolerance to birch pollen-related foods will be evaluated by employing oral challenge tests with the major apple allergen Mal d 1. The composition, specificity and diversity of allergen-specific antibody and T cell responses will be monitored in blood samples from the individuals collected before and at different time points during SIT.

Study design

The study comprises two parts:
1. Department of Allergy, Rotterdam: Analysis of the clinical success of routine allergy treatment using birch pollen (BP) and/or house dust mite (HM) extract (3-5 years). The study will focus on the first two years of treatment, thereby identifying patients responsive or non-responsive to SIT.
2. Medical University of Vienna: In vitro immunological analyses of SIT-responders and non-responders.

Intervention

Routine subcutaneous allergen specific immunotherapy with BP and/or HM extracts

Study burden and risks

Potential burden and risks are associated with those investigations not being part of daily clinical care.
- Patients with BP allergy: Nasal challenge tests with BP extract before and after 12 and 24 months of SIT (2 hours per visit). Nasal challenges may induce upper airway symptoms: itching, sneezing, nasal discharge and blockage. Oral challenge tests with apple and Mal d 1 before and after 12 and 24 months of SIT (Mal d 1/placebo: 2 visits of 2 hours per visit, apple: 1 hour). The challenge with Mal d 1 or apple may cause a so-called oral allergy syndrome: itching, tingle or soreness of lips, mouth, throat, ears, sneezing. Systemic reactions are not expected. Skin tests (20 minutes) and blood sampling are planned at 3 and 5 time-points respectively. In total 15 visits in 24 months are foreseen in patients with concomitant apple allergy, in patients without apple allergy 6 visits are planned .
- Patients with HM allergy: Nasal challenge tests with HM extract before and after 12 and 24 months of SIT (2,5 hours per visit). The nasal challenge may induce upper airway symptoms: itching, sneezing, nasal discharge and blockage. Skin tests (20 minutes) and blood sampling are planned at 3 and 5 time-points respectively. In total 7 visits in 24 months are foreseen.
- If patients are undergoing treatment with both SIT BP and HM, they may take part in both studies to BP and HM responsiveness. This is however not obligatory
Benefits for the patient: At an individual level patients will be better informed about the degree of their individual allergies. In addition, they will obtain an objective evaluation of the clinical success of SIT after 12 and 24 months. At a group level information the efficacy of SIT with BP on birch pollinosis as well as on associated food allergy will be evaluated. Information on the efficacy of SIT with HM will also be obtained. Moreover, insights on immune mechanisms underlying the induction of clinical tolerance to allergens will be obtained. Possibly, the study will identify biomarkers indicating whether SIT is effective or not at an early time point of treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

18 years or older
Clinically relevant moderate to severe allergic rhinitis due to a sensitization for one or two allergens: birch pollen (BP), and/or house dust mite (HM).
Positive nasal challenge test to the relevant allergen (BP and/or HM)

Exclusion criteria

Severe/instable asthma
Previous immunotherapy
General contraindications to immunotherapy (according to international guidelines; i.e. history of anaphylaxis; immunosuppressive treatment etc).

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-09-2012
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	26-07-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-11-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL40576.078.12