Predicting Outcome in Pollen Immuno Therapy

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We will study the differences of nasal epithelial cells of patients who respond vs. who do not respond successfully to the immunotherapy for grass pollen. With this knowledge we can in the future predict or patients will respond successfully or not...

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

Summary

ID

NL-OMON36093

Source
ToetsingOnline

Brief title
the POPIT-study

Condition

- Allergic conditions

Synonym
hay fever, pollenosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: AllergoPharma

Intervention

Keyword: allergen vaccination, allergic rhinitis, epithelium, treatment respons

Outcome measures

Primary outcome

The differences between the expression at the RNA level in nasal mucosa and the possibility to predict the effect of immunotherapy with specific expression profiles.

Secondary outcome

VAS score during nasal provocation before and after immunotherapy

Quantitative skin prick test before and after immunotherapy

Study description

Background summary

Allergy is a common disease. Patients respond to innocent materials in their surroundings, like grass pollen or house dust mite. The symptoms are aspecific, like a runny or stuffy nose, sneezing and running eyes. These symptoms have a big impact on the daily live of the patient. There are medicine which suppress the symptoms, but they do not cure the disease. An alternative is treatment with immuno therapy (IT). With IT, the materials that cause the symptoms are injected subcutaneously. This way, the body gets used to these allergens so the will hopefully cause less symptoms and at the end not anymore at all.

This method, which successful used as treatment for allergies and asthma has also disadvantages. The treatment period is long, about a year, the injections are unpleasant and the results of the treatment are not predictable.

Study objective

We will study the differences of nasal epithelial cells of patients who respond vs. who do not respond successfully to the immunotherapy for grass pollen. With this knowledge we can in the future predict or patients will respond successfully or not.

Study design

All participants will get a skin prick test to begin with. The study will take a year, in which the participants have to visit the hospital regularly. At the first visit we will perform a nasal biopsy with local anaesthesia. Then we will start the immunotherapy with grass pollen. The first seven injections are given weekly and with an increasing dose of grass pollen, so the body can slowly get used to the grass pollen. Depending of the response to the injections, after seven weeks the injections will be given at monthly basis. After a year we evaluate the effect of the immunotherapy.

Study burden and risks

All participants risk a small nose bleeding after the nasal biopsy. The allergic participants will develop an allergic response after the nasal provocation with grass pollen, comparable with the reaction after natural exposure to grass pollen. There is a risk of a local or systemic reaction after the immunotherapy, similar to the risk with clinical treatment with immunotherapy.
All participants will be observed in the hospital for 30-45 minutes and get clear instructions want to do at home when late reactions occur.

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

Clinical relevant allergic rhinitis complaints caused by grass pollen

Exclusion criteria

Immunodeficiencies
Pregnancy
Severe heart and vasculair diseases
Renal failure

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-03-2012
Enrollment:	30

Type:	Actual

Ethics review

Approved WMO Date:	07-11-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL36951.018.11