Monitoring allergen immunotherapy in allergic rhinitis; is nasal fluid the way to precision medicine?

Published: 01-09-2021
Last updated: 28-09-2024

This project will investigate whether a BAT with nasal fluid is suitable for predicting therapy effect at an early stage.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Allergic conditions
Study type	Observational non invasive

Summary

ID

NL-OMON52036

Source
ToetsingOnline

Brief title
Monitoring allergen immunotherapy in allergic rhinitis.

Condition

- Allergic conditions

Synonym
hay fever, rhinitis

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: OCENW.XS21.2.061

Intervention

Keyword: allergen immunotherapy, biomarker, rhinitis

Outcome measures

Primary outcome

Comparison of BAT outcomes (degree of inhibition) with nasal fluid BAT and serum BAT of treated and control patients at baseline and during AIT at 8 and 16 weeks.

Secondary outcome

Correlation between the degree of inhibition in the BAT with the degree of increase of IgG4/IgA-associated inhibitory activity in nasal fluid and serum on IgE-FAB to B-cells.

Study description

Background summary

Allergic rhinitis (hay fever) can be treated successfully with allergen-specific immunotherapy (AIT) for 3-5 years. This relative expensive and prolonged treatment is not suitable for everyone and therefore it is important to predict who will benefit from this therapy early after the start of treatment. Biomarkers, like Basophil Activation Test (BAT) and IgE-facilitated allergen binding (FAB), using nasal fluid instead of blood, probably better reflects therapy effect (inhibition of an IgE-mediated allergic reaction) as the nose is the main target organ for AIT in allergic rhinitis.

Study objective

This project will investigate whether a BAT with nasal fluid is suitable for predicting therapy effect at an early stage.

Study design

A pilot observational study. Nasal fluid and blood samples are collected at baseline (before start AIT) and after 8 and 16 weeks of treatment. A nasal

fluid inhibition BAT is developed and validated by comparison with a BAT using serum and an IgE-FAB assay.

Study burden and risks

Nasal fluid and blood sampling will take place according to standard procedures. Risks of participation include the regular risks involved in the sampling procedures; i.e. irritation and a dry feeling in the nose (collection of nasal fluid) and pain and bruises (collection blood samples).

Contacts

Public
Rijnstate Ziekenhuis

Wagnerlaan 55
Arnhem 6815 AD
NL
Scientific
Rijnstate Ziekenhuis

Wagnerlaan 55
Arnhem 6815 AD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

a. Age >= 18 years
b. IgE-sensitized birch pollen allergic based on:
- sIgE tree pollen > 10 kU/L
- seasonal related allergic rhinitis
c. Start of Itulazax therapy or standard therapy (nasal corticosteroid and/or antihistamine eye drops)
d. Signed informed consent.

Exclusion criteria

a. Age < 18 years
b. Other underlying chronic conditions (immunological (autoimmune or immunodeficiency), oncological)
c. Unstable uncontrolled asthma
d. Smoking.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-09-2023
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	01-09-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-10-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL78278.091.21