# Biomarkers in ALlergic diseases and allergen Immunotherapy

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

## Summary

### ID

NL-OMON45948

**Source**
ToetsingOnline

**Brief title**
BALI

### Condition

- Allergic conditions

**Synonym**
allergy, immunotherapy

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Franciscus Ziekenhuis
**Source(s) of monetary or material Support:** De kosten worden verdeeld door de stichting O&O van het Franciscus Gasthuis en Imperial College in Londen

## Intervention

**Keyword:** Allergy, Biomarkers, Immunotherapy

## Outcome measures

### Primary outcome

Predictive value of candidate biomarkers sIgE/tIgE and IgE-FAB on

treatment-effect.

### Secondary outcome

• Correlate the biomarker sIgG4 with compliance.

• Identify novel candidate biomarkers involved in the mechanisms of AIT.

• Correlate novel candidate biomarkers with treatment response.

• Compare local vs systemic biomarkers

# Study description

### Background summary

Allergen Immunotherapy (AIT) has been proven to have disease-modifying properties and long-term clinical benefit after cessation in patients with or without allergic asthma. However, some patients do not respond optimally. To date there is no consensus on candidate biomarkers that are predictive of the clinical response to AIT. In addition, a recent position paper by an EAACI taskforce advises to start research initiatives in order to correlate candidate biomarkers to responders and non-responders.

### Study objective

We aim to identify the predictive value of the candidate biomarkers suggested by the EAACI taskforce for response to AIT. Additionally, we aim to explore novel candidate biomarkers both for clinical follow up as well as contribute to unravelling the mechanism of AIT.

### Study design

This research project is twofold. Firstly: an observational, prospective cohort

design to test the predictive value of the suggested biomarkers. Secondly: a case-control design to explore novel candidate biomarkers and obtain more insight in the mechanism involved in AIT.

**Study burden and risks**

Patients will be asked to donate 200ml of full blood per visit (7 visits in total). This can cause a bruise or hematoma at the site of the venepuncture which is considered a low risk event. Feeling light-headedness which in some cases can lead to syncope is also a possibility. Furthermore, patients will be asked to fill out two questionnaires per visit (CARAT and ACQ), requiring ten minutes total per visit for both questionnaires.

## 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

1. Positive Skin Prick Test (SPT) response of >= 8 mm wheal diameter and/or serum allergen-specific IgE levels higher than 0.70 kU/L to grass pollen, tree pollen and/or house dust mite (HDM) extract.
2. Minimum of 18 years of age and a confirmed clinical diagnosis of allergic rhinitis.
3. Clinical indication for AIT.
4. Signed and dated informed consent (IC) form by a legally competent participant.

## Exclusion criteria

1. History of chronic autoimmune disease (aside from asthma, atopic dermatitis or allergic rhinitis) which may interfere with results.
2. Use of an antihistamines or decongestant therapy 7 days prior to screening visit.
3. Prior exposure to any monoclonal antibody treatment within the past 12 months.
4. Contraindication to sublingual or subcutaneous AIT.
5. Current immunosuppressive treatment.
6. Current pregnancy or breastfeeding, active pregnancy wish.
7. Previous immunotherapy with grass pollen, tree pollen or house dust mite extract.

# Study design

## Design

**Study type:** Observational non invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Basic science |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 20-01-2020 |
| Enrollment: | 160 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 11-04-2019 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28588
Source: NTR
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL67580.100.18 |
| OMON | NL-OMON28588 |