BALI-study

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28588

Source
Nationaal Trial Register

Brief title
BALI

Health condition

Allergic Rhinitis

Sponsors and support

Primary sponsor: Franciscus Gasthuis & Vlietland
Imperial College London
Source(s) of monetary or material Support: Sponsor

Intervention

Outcome measures

Primary outcome

Clinical response to AIT will be considered as a binary outcome (yes/no) and will be monitored by:

- Control of Allergic Rhinitis and Asthma Test (CARAT) (Appendix 1).

- Requirement of medication related rhinitis and/or asthma treatment. This includes oral first-

and second-generation anti-histamine, nasal corticosteroid, bronchodilators, inhaled corticosteroid (ICS), and ICS + long-acting ¦Â2-agonist (LABA);

- Asthma Control Questionnaire (ACQ) (Appendix 2). The MCID of the ACQ is 0.5 points.

- Frequency of asthma exacerbations.

Secondary outcome

We will explore the prevalence the use of allergen-specific IgG4 (sIgG4) as a biomarker for compliance.

Apart from the suggested candidate biomarkers the project will focus on novel candidate biomarkers both for clinical follow up as well as unravelling the mechanism of AIT. For this exploratory research novel techniques, such as for example genomics and proteomics, will be used to explore for new candidate markers.

Biomarkers that can be explored may include:

- Humoral biomarkers

- Cytokine markers.

Study description

Background summary

Rationale: 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.

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 population: Patients with allergic rhinitis, with or without asthma, starting AIT for the first time in their regular (outpatient) treatment. Patients will be recruited at the outpatient clinic for lung diseases and allergies.

Main study parameters/endpoints: Predictive value of candidate biomarkers sIgE/tIgE and IgE-FAB on treatment-effect.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Study objective

sIgE/tIgE and IgE-FAB can be used to predict the clinical response to AIT.

Study design

T0 = at start of AIT

T1 = 6 months after start of AIT

T2 = 12 months after start of AIT

T3 = 2 years after start of AIT

T4 = 3 years after start of AIT (= stop AIT)

T5 = 1 year after stopping AIT

T6 = 3 years after stopping AIT

Intervention

No intervention. We collect blood through venapuncture and nasal fluid through nasal swabs.

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

- 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.

- Minimum of 16 years of age and a confirmed clinical diagnosis of allergic rhinitis.

- Clinical indication for AIT (according to EAACI guidelines).

Signed and dated informed consent (IC) form by a legally competent participant.

Exclusion criteria

History of chronic autoimmune disease (aside from asthma, atopic dermatitis or allergic rhinitis) which may interfere with results.

Use of an antihistamines or decongestant therapy 7 days prior to screening visit.

Prior exposure to any monoclonal antibody treatment within the past 12 months.

Contraindication to sublingual or subcutaneous AIT.

Current immunosuppressive treatment.

Previous immunotherapy with grass pollen, tree pollen or house dust mite extract.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2019
Enrollment:	160
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 45948
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7312
NTR-old	NTR7528
CCMO	NL67580.100.18
OMON	NL-OMON45948

Study results