BALI-study

Gepubliceerd: 03-10-2018 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28588

Bron
NTR

Verkorte titel
BALI

Aandoening

Allergic Rhinitis

Ondersteuning

Primaire sponsor: Franciscus Gasthuis & Vlietland
Imperial College London
Overige ondersteuning: Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2019
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45948
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten