Screening potential allergy vaccine components

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In the frame of three projects at Amsterdam UMC, we are exploring possibilities to improve AIT for both respiratory and food allergy. We have combined these three projects in a single protocol because experiments to be carried out with moDCs...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24623

Bron
NTR

Verkorte titel
Blood4MODC

Aandoening

Allergy

Ondersteuning

Primaire sponsor: Investigator initiated- Amsterdam university medical centers
Overige ondersteuning: Health Holland under the TKI-PPP and Angany, a Canadian biotech company from Quebec City

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The aim of the study is to obtain a blood sample for isolation of monocytes. These monocytes

will be used to generate monocyte-derived dendritic cells (moDC).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Allergen immunotherapy (AIT) is the only disease-modifying treatment for IgE-mediated allergies, but the long treatment duration required (3-5 years) and the risk of potentially severe adverse events are major disadvantages that limit its application.

Objective: The objective of the study is to collect blood samples for generation of monocyte-derived DCs (moDCs) and to use these antigen-presenting cells to evaluate the immune-skewing potential of different combinations of nanoparticles, purified allergens, adjuvants and targeting reagents. The ultimate goal is to find combinations that increase safety (by lowering allergenic potency) and increase efficacy of induction of anti-inflammatory protective responses, both with respect to kinetics and effect size.

Study design: This is a non-interventional study in which blood samples are obtained to facilitate in vitro cellular analyses.

Study population: The study population consists of adult (18-65 yrs) allergic rhinitis subjects and two groups of adult subjects, i.e. non-allergic rhinitis subjects and healthy subjects.

Intervention (if applicable): Not applicable.

Main study parameters/endpoints: The main study parameter is successful generation of sufficient moDCs from (multiple) voluntary blood donations of minimally 50 ml to maximally 200 ml of fresh blood, from a total of 50 donors.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Subjects will contribute to increasing the knowledge in the field of innovation of AIT for the treatment of allergic diseases. In the future this may provide new safer and more effective treatments that benefit the allergic patient. Disadvantage and risks of participating are minimal. Blood drawing can cause a low level of pain and may occasionally result in a hematoma.

Doel van het onderzoek

In the frame of three projects at Amsterdam UMC, we are exploring possibilities to improve AIT for both respiratory and food allergy. We have combined these three projects in a single protocol because experiments to be carried out with moDCs generated from the obtained blood samples will be used in identical experiments. In fact, candidate vaccine components from the three different projects can and will be compared in single experiments to establish which (combination of) approaches is most promising to improve AIT. One study focuses on the use of nanoparticles: liposomes of various composition and PLGA nanoparticles as

alternative for aluminum hydroxide. By loading the liposomes/nanoparticles with allergen, it is shielded from contact with mast cells when injected, decreasing the risk of side-effects. The second study on the central hypothesis of the project is that sialylated antigens/allergens effectively induce a regulatory anti-inflammatory immune response, and the last on plant bioparticles that are expressing allergens on the surface and are rich in glycosylceramide which is thought to induce anti-inflammatory responses.

Onderzoeksopzet

If the subject is prepared they can give 50-200 ml of blood on multiple occasions (up to maximally 20 times in 4 years)

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

There are three categories of subjects for blood donation:

 Subjects with doctor-diagnosed allergic rhinitis

 Subjects with doctor-diagnosed non-allergic rhinitis
 Healthy subjects, defined as not having allergic or non-allergic rhinitis or other inflammatory non-communicable diseases such as rheumatoid arthritis, type 2 diabetes, celiac disease, colitis ulcerosa, Chrohn’s disease, and multiple sclerosis.

All three categories should meet the following additional criteria:

• Age between 18 and 65.
• Signed informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• History of AIT (SCIT or SLIT) with any allergen within the past year at the time of blood donation.
• Ongoing AIT (SCIT or SLIT) with any allergen at the time of blood donation.
• Vaccination within one week before blood donation.
• Immunosuppressive or biological medication (e.g. IL-5, anti-IgE therapy) within the last six months prior to blood donation.
• Severe immune disorders (including auto-immune diseases) and/or diseases requiring immunosuppressive drugs.
• Active malignancies or any malignant disease during the previous 5 years.
• Active inflammation or infection at the time of blood donation.
• Use of systemic steroids within 4 weeks before the blood donation.
• Treatment with systemic and local β-blockers.
• Subjects who are students or employees of the institution or 1st grade relatives or partners of the investigators.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	31-01-2020
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
moDCs generated from the obtained blood samples will be used in identical experiments. In fact, candidate vaccine components from the three different projects can and will be compared in single experiments to establish which (combination of) approaches is most promising to improve AIT. So, no individual patient data will be shared, but results with the MoDCs will be published.

Ethische beoordeling

Positief advies

Datum:	13-01-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8292
Ander register	METC AMC : METC 2019_202

Resultaten

Samenvatting resultaten
see above