Nutrition-based approach to support antigen-specific immunotherapy in subjects with cow's milk or peanut allergy

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To study the immunomodulatory effects of non-digestible oligosaccharides using peripheral blood mononucleated cells isolated from blood of healthy controls and patients with peanut or cow*s milk allergy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Observational invasive

Summary

ID

NL-OMON43691

Source
ToetsingOnline

Brief title
Nutrition-based approach for antigenspecific immunotherapy for food allergy

Condition

- Allergic conditions

Synonym
Food Allergy

Research involving
Human

Sponsors and support

Primary sponsor: Dermatologie/Allergologie

Source(s) of monetary or material Support: STW

Intervention

Keyword: Food Allergy, Fructo-oligosaccharides, Galacto-oligosachharides, Immunotherapy

Outcome measures

Primary outcome

The T-cell response (measured by cytokine production) and phenotype of these cells (Th1/Th2/Treg by flow cytometry) in patients before and after stimulation of their isolated cells from blood with specific allergen (whey or peanut) and the influence and effect of NDOs on this response (with/without presence of artificial CpG DNA or Bifidobacterium breve DNA)

Secondary outcome

Changes in cytokine and chemokine profile of PBMCs after stimulation with NDOs will be studied. Also changes in cytokine and proliferation within subpopulations of the PBMCs will be studied (e.g. Dendritic cells or T-cells) and the interaction between these groups. To study safety of the NDOs, the activation of basophils will also be monitored.

Study description

Background summary

Food allergy is an important socio-economic problem which is estimated to occur in 2-3% of the population. Current treatment encompasses symptomatic treatment and elimination diets. Human studies have shown encouraging results when treating subjects with subcutaneous or oral administration of allergy-related proteins. However, adverse effects are not uncommon and these forms of immunotherapy have not yet resulted in sustained unresponsiveness. Recent in vitro studies, as well as studies in children and mice have indicated that a mixture of dietary non-digestible oligosaccharides (NDOs) either or not

together with immune polarizing adjuvants like bacterial CpG DNA may improve the efficacy and safety of immunotherapy in allergic patients.

Study objective

To study the immunomodulatory effects of non-digestible oligosaccharides using peripheral blood mononucleated cells isolated from blood of healthy controls and patients with peanut or cow*s milk allergy.

Study design

Subjects will be asked questions about their allergic history by the researcher and recent usage of corticosteroids and antihistamine prior to blood withdrawal of a variable amount of 60-100 mL. A sample of blood will be taken from a vein in the arm (venepuncture). The technique for obtaining blood frequently involves the use of various-sized vacuum tubes specific for collecting blood. Clinical investigators will collect 60-100 mL blood from adults. The blood will be processed by the PhD student as soon as possible for laboratory tests.

Study burden and risks

The most common side effect is a small discoloration or bruise that may remain at the site for several days. There may be mild temporary pain associated with insertion of the needle. In very rare cases, a local infection may occur at the site of the venipuncture. The subject will be informed that there may be some slight pain and discomfort with the blood withdrawal.

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

Patients with established cow*s milk or peanut allergy (determined by food provocation) in the age of 18-65 years from our outpatient clinic Allergology/Dermatology

Exclusion criteria

Pregnancy and use of systemic immunosuppressants (the continuous use, not local usage as an effect of an allergic reaction, e.g. prednison)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-02-2016

Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	12-06-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-09-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL51606.041.15