Study on IgE Memory B cells in Allergic disease

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

Summary

ID

NL-OMON39979

Source
ToetsingOnline

Brief title
SIMBA

Condition

- Allergic conditions

Synonym
allergy, type I hypersensitivity responses

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Sophia Kinderziekenhuis Fonds

Intervention

Keyword: allergen, allergy, B-cell, IgE

Outcome measures

Primary outcome

From each patient, the absolute B- and T-cell numbers in blood (cells per milliliter of blood) will be determined, as well as the relative frequencies of naïve and IgM+, IgG+, IgA+ and IgE+ memory B-cells. Total and allergen-specific serum IgE levels will be determined. These parameters will be compared between patients with food allergy, patients with asthma, patients with hay fever and healthy controls. Finally, we will study the correlation of IgE+ memory-B-cell numbers with serum IgE levels and the IgE allergen-specificity.

Secondary outcome

Relate the changes in the B-cell compartment and serum IgE levels to changes in T-cell subsets, eosinophils, basophils and mast cells in blood. Since the anatomical location differs between asthma/hay fever, atopic dermatitis and food allergy, we hypothesize that distinct B cells are involved.

Study description

Background summary

Immunoglobulin E (IgE) antibodies mediate the onset of a wide range of allergic disorders through their recognition of allergens. IgE is on of the five antibody isotypes produced by terminally differentiated B-cells. The commitment of a B-cell to isotype class switch to an IgE-producing cell is a tightly regulated process. In healthy individuals, IgE-producing B-cells are very infrequent and therefore hardly detectable. We recently identified two distinct IgE+ memory B-cell populations in blood of healthy donors: CD27+IgE+ and CD27-IgE- B-cells. CD27-IgE- B-cells are derived from T-cell dependent

responses and CD27+IgE+ from T-cell independent responses. Studies on these distinct IgE+ populations can provide new insights into the processes underlying allergic reactions

Study objective

We wish to study the absolute numbers, ratio and phenotype of CD27+IgE+ and CD27-IgE+ memory-B-cells in blood of atopic children who suffer from proven IgE-mediated asthma/hay fever, atopic dermatitis or food allergy and compare these with healthy non-atopic children. Furthermore, these B-cell numbers will be correlated to allergen-specific and total serum IgE levels. Finally, patients will be grouped based on their IgE allergen-specificity (food or inhalant) and IgE+ B-cell numbers will be compared between these groups of patients.

Study design

We will study different immune cells in blood of patients between 6-18 years of age with proven asthma/hayfever, atopic dermatitis and foodallergy and in blood of age-matched healthy controls. With a newly developed flow cytometric approach we can for the first time study abnormalities in IgE+ B cells of allergic patients and compare these values with non-allergic healthy age matched controls. We will relate our findings in the IgE+ B cell compartment with other immune cells involved in allergic reactions, i.e. other B-cell subsets, T-cells and eosinophils.

The study will be cross-sectional, observational with 1x collection of blood. Already obtained values of healthy non-allergic children and young adults will be used as age-matched controls.

Study burden and risks

We will plan one visit for the patient to the outpatient clinic (if possible this will be scheduled at a regular follow-up visit) to draw 1 blood sample of 7ml heparinized blood. The total burden will thus be one venipuncture, and occasionally one extra clinic visit. There are no additional health risks, because there is no intervention.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

* children from 6-18 yrs old with asthma/rhinitis, atopic dermatitis or food allergy
* Atopy with proven allergen (RAST class >1.4 or specific IgE serum levels > 0.7 IU/L or positive skin prick test with HEP index > 0.21)
* Positive doubleblind food provocation test or convincing history of recent adverse response to food intake
* Informed written consent

Exclusion criteria

- Patients < 6 yrs old
- Children who are receiving immunosuppressive therapy
- Children with substantial co-morbidity of immune-related diseases, especially immunodeficiencies or autoimmune disease (e.g. diabetes)
- Children receiving anti-IgE antibody treatment (e.g. with Xolair)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-01-2013
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	10-10-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-04-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL39649.078.12