Prospective evaluation of allergen-component resolved diagnostic allergy testing and its relation to clinical features of allergic disease in children

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

Summary

ID

NL-OMON38409

Source
ToetsingOnline

Brief title
CRD-Isala

Condition

- Allergic conditions

Synonym
allergic disease, allergy

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken

Source(s) of monetary or material Support: Thermo Fischer,unrestricted educational grant van fabrikant allergietest (Thermo Fischer); tevens eigen middelen

Intervention

Keyword: allergy, children, component resolved diagnostics, IgE

Outcome measures

Primary outcome

relationship between component resolved diagnostics (specific IgE against components of major inhalant and food allergens) and symptoms of allergic disease in children (atopic dermatitis, asthma, allergic rhinitis, and food allergy)

Secondary outcome

not applicable

Study description

Background summary

The diagnostic possibilities in childhood allergies are rapidly changing. Only a few years ago, sensitization to specific whole allergens was considered to be diagnostic of allergy. More recent studies have shown that allergen sensitization is not always accompanied by clinical reactivity to the allergen, in particular to foods. This has been particularly well documented for peanut sensitization in children, where the large majority of children sensitized to whole peanut allergen do not show allergic symptoms when ingesting peanut orally. Because of the unclear relationship between peanut sensitization and clinical peanut allergy, prevalence rates of parent-reported food allergy in children vary considerably between surveys. Accumulating evidence suggests that component resolved diagnostics (CRD), i.e. testing of sensitization to specific allergen components instead of testing sensitization to the whole allergen, may improve the relationship between sensitization and clinical allergy in children. For example, the sensitivity and specificity of specific immunoglobulin E (IgE) to the peanut allergen Ara h2 to oral food challenge outcome in children has been reported as 60% and 98%, respectively.These were preliminary studies comparing children with and without known peanut allergy,

however. The use of CRD in other food allergies and in inhalant allergies is in its infancy. Further studies are therefore needed to evaluate the relationship of CRD to clinical allergy in children.
Although guidelines on the diagnosis of allergic disease in children are available, both nationally and internationally, these documents differ considerably, reflecting the rapidly changing possibilities and viewpoints regarding the usefulness of allergy testing in clinical practice. For example, whilst the 2010 revision of the Dutch general practitioners* guideline of the diagnosis of food allergy recommends not to use specific IgE testing to foods because of their limited ability to predict clinical food allergy, most international practice guidelines suggest that the diagnosis of food allergy may be reliably made based on a suggestive history, combined with evidence of atopic sensitization to the relevant allergen. These striking differences between guidelines are likely to leave primary and secondary care clinicians confused as to the true role of specific IgE testing in the diagnostic work-up of allergic diseases in clinical practice. It is likely that the improved diagnostic accuracy of specific IgE testing by splitting up allergen responses into responses to different allergen components will be helpful in diminishing this confusion, but this must be supported by high-quality data from a large and representative patient sample.

Study objective

by improving the understanding of the relationship of CRD to clinical expressions of allergic disease in children, this study aims at generating data that can improve the development of tools that will help the primary or secondary care practitioner to interpret results of specific IgE testing to allergens and their components in a clinically meaningful context.

Study design

prospective cohort study

Study burden and risks

minimal burden (once only additional blood sampling of 10 ml of blood; no additional venipuncture; once only completion of questionnaires by parents), no risk

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

- each child (0-17 years of age) referred (by general practitioner or hospital-based medical specialist) to the Isala laboratory for "allergy testing"
- written informed consent from parents/caregivers

Exclusion criteria

- no parental consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2014
Enrollment:	1000
Type:	Anticipated

Ethics review

Approved WMO

Date:	04-02-2014
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL47002.075.13