Can the sensitization profile towards hazelnut, peanut and birch pollen be used to predict the severity of clinical symptoms of hazelnut allergy in both children and adults?

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To analyze whether the sensitization profile towards hazelnut, peanut and birch pollen and their major individual allergens can be used to predict whether the hazelnut allergy is associated without/with mild clinical symptoms or severe clinical...

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

Summary

ID

NL-OMON35609

Source
ToetsingOnline

Brief title
Prediction model to predict the clinical severity of hazelnut allergy.

Condition

- Allergic conditions

Synonym
food allergy, hazelnut allergy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cross-reactivity, Food allergy, Hazelnut allergy, prediction model

Outcome measures

Primary outcome

Based on literature and preliminary data, four determinants are identified, which we think are (most) predictive for the severity of the symptoms of hazelnut allergy. The determinants are: Cor a 1, Cor a 8, Cor a 9 and oleosin. First, the predictive value of each determinant will be assessed using univariate analysis. Second, a multivariable logistic regression model will be build starting with the strongest predictor (based on the relative risk obtained from univariate analysis).
To make the prediction model applicable for clinical practice, a prediction rule will be made and for the different possible scores on the prediction rule (or categories of the score), we will present the probability of having severe symptoms of hazelnut allergy.

Secondary outcome

The analysis of IgE and T cell cross-reactivity concerns a secondary analysis to define potential mechanisms responsible for the difference in clinical severity of symptoms. We determine whether there are genetic associations by analysing these polymorfisms.

Study description

Background summary

Together with other tree nuts and peanut, hazelnut accounts for 90% of fatalities due to food allergy. Hazelnut allergy is present in both children and adults. Children with hazelnut allergy, have more frequently severe symptoms compared to adults with hazelnut allergy. There are indications that differences in the clinical spectrum are related to differences in allergen recognition. Mild symptoms for hazelnut have been associated with hazelnut allergens that are cross-reactive with birch pollen. Severe symptoms for hazelnut are possibly related to hazelnut allergens that are cross-reactive with peanut and other tree nuts. These co-sensitizations could be the result of IgE cross-reactivity between homologous allergens in hazelnut, peanut and birch pollen. There are indications that this sensitization profile is different in children compared to adults. Preliminary data suggest that in children sensitization for the hazelnut allergen Cor a 8, which is homologous to Ara h 9 in peanut, is correlated to severe hazelnut allergy. In contrast, adults with severe hazelnut allergy have hardly any Cor a 8 sensitization. It would be helpful if the sensitization pattern could be used to predict (the severity of) the hazelnut allergy. The preliminary data suggest that this predictive pattern may differ between children and adults. The mechanism underlying the diversity of the clinical symptoms is badly understood.
Recent discovered polymorfisms in genes, which are important for skin and lung barrier function and regulation of immune responses, predispose for atopy. These polymorfisms could play a role in the route of sensitization and the prediction of the severity of the hazelnut allergy.

Study objective

To analyze whether the sensitization profile towards hazelnut, peanut and birch pollen and their major individual allergens can be used to predict whether the hazelnut allergy is associated without/with mild clinical symptoms or severe clinical symptoms. Additionally, analysis of potential cross-reactivity between hazelnut, peanut and/or birch pollen, may provide inside into the primary sensitizing allergen and the route of sensitization. This may help to understand the mechanism leading to the observed diversity in the severity of hazelnut allergy.

Study design

Serum and peripheral blood mononuclear cells (PBMCs) will be collected from children and adults with a hazelnut sensitization without/with mild or severe clinical symptoms. The sensitization profile towards hazelnut, peanut and birch pollen (both total extract and major allergens) will be analysed by CAP,

immunoblot, allergen chip and basophil activation test. The role of cross-reactivity and the primary sensitizing allergen will be analysed by immublot and CAP-inhibition assays. Whether cross-reactivity at the T cell level underlies cross-reactivity at the IgE level will be investigated by analysis of the allergen-specific response in hazelnut-, peanut- and birch pollen-specific T cell lines towards cross-reactive allergens. We will use a protein-truncation test, PCR and sequencing to determine the polymorfisms.

Study burden and risks

Blood will be collected from children and adults participating in this study (10 ml 3-6 years, 30 ml 7-11 years, 40 ml 12-15 years and 60 ml >16 years). Children with a high risk upon an allergic reaction during DBPCFC will get a drip, this is a standard procedure. High risk is defined as an anaphylactic shock or dyspnoea after hazelnut ingestion according to the history or a hazelnut CAP > 15 or SPT from 2+ or more. In these children the blood will be collected from the drip. Children from 3-6 years will not be exposed to a venepuncture. Children from 7 years, without a blood collection during the DBPCFC and adults will get a venepuncture for blood collection. This can cause some pain and can result in a small haematoma.

Contacts

Public
Selecteer

Heidelberglaan 100
3584 CX Utrecht
NL
Scientific
Selecteer

Heidelberglaan 100
3584 CX Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

children and adults with a hazelnut sensitization

Exclusion criteria

congenital/aqcuired immunodeficiency
lymphoproliferative disease
systemic immunosuppression
insufficient knowledge of Dutch language
children from 3-6 years will be excluded from genetic research

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-02-2010
Enrollment:	176
Type:	Actual

Ethics review

Approved WMO Date:	29-09-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	09-03-2010
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	NL27799.041.09