Basophil degranulation assay as an in vitro model of anaphylaxis

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Primary objective: To evaluate if the supernatant of allergen challenged basophils from non-systemic sensitized patients result in little, if any, activation of indicator basophils, whereas the supernatant of allergen challenged basophils from…

Ethical review	Approved WMO
Status	Will not start
Health condition type	Allergic conditions
Study type	Observational invasive

Summary

ID

NL-OMON38967

Source
ToetsingOnline

Brief title
BDA

Condition

- Allergic conditions

Synonym
Hymenoptera venom allergy, insect venom allergy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Anaphylaxis, Basophil degranulation assay, In vitro model

Outcome measures

Primary outcome

CD63 and CD203c expression on basophils.

Secondary outcome

Detection and comparison of factors in supernatant of basophils from

anaphylactically sensitized patients compared to non-anaphylactically

sensitized patients.

Study description

Background summary

Patients with a history of an anaphylactic sting reaction and a positive skin-prick test and/or positive specific immunotlobulin E (sIgE) only have a risk of 50-60% of a re-systemic reaction. Discrepancies between sensitization and clinical allergy form a bottleneck in selecting patients eligible for immunotherapy. Only sting challenges with living insects allow an estimation of the prognosis with respect to the risk of, and severity of a systemic reaction on subsequent stings. we propose to develop a functional in vitro assay to predict anaphylactig reaction in vivo.

Study objective

Primary objective: To evaluate if the supernatant of allergen challenged basophils from non-systemic sensitized patients result in little, if any, activation of indicator basophils, whereas the supernatant of allergen challenged basophils from anaphylactically sensitized patients result in considerable activation of indicator basophils.
Secondary objective: To investigate shich fator(s) supernatant contains that could cause the observed basophil degranulation in vitro.

Study design

Observational case-control study

Study burden and risks

There is no risk in relation to the participation in this stud and the burden is minimal, as only at one time point a 20 ml blood sample is drawn.

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

- A clear positive history of a systemic response grade IV or a large local reaction after a vespid sting*
- Vespid specific serum IgE > 0.70 kUA/l or a positive intracutaneous skin test for vespid venom (at <= 1 µg/ml)*
- Written informed consent

*These inclusion criteria do not apply to the indicator subjects

Exclusion criteria

- Age under 18 years
- Incapacitated subjects
- Conditions that influence the immune system (immune deficiencies, malignancy, auto-immune diseases)
- Pregnancy (measured before inclusion by β-hCG)
- Mastocytosis;Extra exclusion criteria for indicator subjects:
- A positive history of a large local or systemic response after a Hymenoptera sting
- Vespid specific serum IgE > 0.30 kUA/l

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:	Will not start
Enrollment:	35
Type:	Anticipated

Ethics review

Approved WMO Date:	14-08-2013
Application type:	First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	NL44083.042.13