Gene expression analysis elucidating pathogenic mechanisms and predicting vespid venom anaphylaxis

Published: 09-08-2013
Last updated: 24-04-2024

Primary Objective: Difference in gene expression profiles in peripheral blood cells between reactors and non-reactors on a sting challenge with corresponding functional annotation and a naïve Bayes prediction model for patients at risk of a re-...

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

Summary

ID

NL-OMON38535

Source
ToetsingOnline

Brief title
GEIVA

Condition

- Allergic conditions

Synonym
Vespid venom allergy, wasp venom allergy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Polish Ministry Grant

Intervention

Keyword: Anafylaxis, Gene expression, Sting challenge, Vespid venom

Outcome measures

Primary outcome

Main study parameter: Genes for which the expression is significantly different between reactors and non-reactors based on a log2 fold change > 2 in gene expression, identify the corresponding functional annotation and building a corresponding naïve Bayes prediction model to identify patients at risk for a re-systemic reaction.

Secondary outcome

Secondary study parameter: Genes for which the expression after the sting challenge is significantly different compared to base line expression levels and identify the corresponding functional annotation.

Study description

Background summary

Patients with a history of anaphylactic sting reactions and a positive allergological work-up including in-vitro tests and/or skin tests have a risk of 50-60% of a re-systemic reaction. Strikingly, this risk is not 100%. Sting challenges allow a more precise prognosis with respect to the risk of, and severity of a systemic reaction on subsequent stings but are hampered by many disadvantages. Gene expression analysis is a promising tool in this field, and might provide a minimally invasive and highly sensitive tool to assess the risk of a re-systemic reaction and elucidate pathways involved in mounting systemic allergic reactions.

Study objective

Primary Objective: Difference in gene expression profiles in peripheral blood cells between reactors and non-reactors on a sting challenge with corresponding

functional annotation and a naïve Bayes prediction model for patients at risk of a re-systemic reaction. Secondary Objectives: Changes in the gene expression profile compared to baseline during an acute systemic allergic reaction with corresponding functional annotation.

Study design

Prospective case-control study.

Intervention

Blood sampling for gene expression analysis before and after the sting challenge test.

Study burden and risks

Subjects participating in the study will visit the UMCG 1 to 3 times for a sting challenge for approximately 3 hours. 7.5 ml of peripheral blood will be drawn before each sting challenge. At the first sting challenge an additional peripheral intravenous line will be placed for the collection of 32.5-87.5 ml of venous blood divided over a set interval. The sting challenge is the gold standard for the diagnosis of insect venom allergy and is a used procedure in the University Medical Center Groningen to select patients eligible for venom immunotherapy. Measures have been taken to reduce the chance of severe systemic reactions by excluding patients at risk and administration of sting challenges under intensive care conditions with an intravenous line at each sting and constant medical attention.

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 II, III or IVa after a vespid sting
* Vespid specific serum IgE > 0.35 kUA/l or a positive intracutaneous skin test for vespid venom (at <= 1 µg/ml a histamine equivalent prick of >=0.7)
written informed consent

Exclusion criteria

* A positive history of a systemic response grade IVb according to Mueller (13) after a vespid sting
* Age under 18 years or above 65 years
* Incapacitated subjects
* Severe cardiopulmonary disease (clinical evidence of congestive heart failure, coronary disease or severe hypertension)
* Insufficiently controlled asthma based on history, asthma control questionnaire and if the observed FEV1 is 70% of predicted.
* Conditions that influence the immune system (immune deficiencies, malignancy, auto-immune diseases, flulike dissease)
* Severe kidney failure
* Interfering medication with the outcome or recovery from a systemic reaction (β-blockers and immunosuppressive drugs)
* Pregnancy(measured before inclusion by β-hCG)
* Mastocytosis

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	09-08-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-07-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-09-2015
Application type:	Amendment
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	NL44251.042.13