A pilot study on efficacy and safety of 100 ug start dose wasp venom immunotherapy (VIT)

Published: 23-04-2013
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zie protocol

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

Summary

ID

NL-OMON38607

Source
ToetsingOnline

Brief title
EVVIT100

Condition

- Allergic conditions

Synonym
insect venom hypersensitivity, wasp 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: Efficacy, Safety, Venom Immunotherapy

Outcome measures

Primary outcome

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Secondary outcome

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Study description

Background summary

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Study objective

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Study design

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Intervention

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Study burden and risks

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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 positive history of a systemic response grade II/III/IVa after vespid sting
- Specific serum IgE > 0.7 kU/
- Positive intracutaneous skin test for vespid venom (at <= 1 µg/ml)

Exclusion criteria

- A positive history of a systemic response grade IVb according to Müller after a vespid sting
- Age under 18 years or above 65 years
- Severe cardiopulmonary disease (clinical evidence of congestive heart failure, coronary disease or severe hypertension)
- Insufficiently controlled asthma, especially if FEV1 is 70% of predicted.
- Conditions that influence the immune system (immune deficiencies, malignancy, auto-immune diseases)
- Severe kidney failure
- Interfering medication with the outcome or recovery from a systemic reaction (β-blockers and immunosuppressive drugs)
- Allergy to auxiliary matter in Pharmalgen® Vespula spp.

- Pregnancy
- Mastocytosis

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-05-2013
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Pharmalgen Wasp Venom
Generic name:	Wasp venom protein
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	23-04-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	09-07-2015
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
EudraCT	EUCTR2013-001102-29-NL
CCMO	NL43093.042.13