Immunomodulatory mechanisms of Venom Immunotherapy

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Although it is known that Tregs have an important role in the induction of tolerance in allergen immunotherapy, more research into the different populations is necessary. The recent developments in FOXP3-stainings together with intracellular...

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

Summary

ID

NL-OMON31868

Source
ToetsingOnline

Brief title
WaspIT

Condition

- Allergic conditions

Synonym
Insect venom allergy OR Yellow jacket allergy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ubbo-Emmius beurs

Intervention

Keyword: Flow cytometry, Foxp3, Regulatory T-cells, Venom Immunotherapy (VIT)

Outcome measures

Primary outcome

Detailed analysis and functional characterization of different regulatory

T-cell subpopulations induced after VIT.

Secondary outcome

Determination of serum IgG, IgA and IgE - levels in correlation with IL-10 and

TGFβ

Study description

Background summary

Venom Immunotherapy (VIT) is an established treatment for the prevention of anaphylactic reactions after insect stings. This protection is acquired after a series of subcutaneous injections of purified wasp venom extracts. The mechanism of tolerance induction is not completely understood, though a role for regulatory T-cells (Tregs) has been shown thoroughly in previous research. In general Tregs are subdivided in naturally occurring Tregs (nTregs) and adaptive Tregs (aTregs). Recent studies, investigating Treg subpopulations, showed aTregs with an nTreg phenotype, and Tregs with a combination of both nTregs and aTregs phenotypes. These findings make us wonder about the original Treg subdivision, and their relation in suppression of allergic reactions.

Study objective

Although it is known that Tregs have an important role in the induction of tolerance in allergen immunotherapy, more research into the different populations is necessary. The recent developments in FOXP3-stainings together with intracellular cytokines (IL-4, IL-10, TGFβ and IFNγ) in the CD3+CD8- - allergen specific (CD154+) population, make it possible to make a clear distinction between the different Treg subtypes. Analysis of the function of these subtypes can be evaluated by co culturing experiments.

Study design

Observational cohort study with patients routinely undergoing VIT in the allergy clinic of the UMCG Groningen. At three timepoints, before, 6 weeks and 6 months after the start of VIT, blood samples will be obtained, in which T-cell - populations and their function, and Immunoglobulin*s will be studied.

Study burden and risks

The charge and risks of this study compaired with the VIT routinely carried out are minimal.
The only charge is the extra blood collected during the study. This happens at 3 times; before, 6 weeks and 6 months after starting the therapy.
No extra risks are enclosed in this study.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
9713 GZ Groningen
Nederland
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
9713 GZ Groningen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

-Severe systemic reaction after a wasp sting (Müller III - IV)
-Positive Intracutaneous Skin Test for Wasp Venom (HEIC>= 0.5 at 1 ug)
-Specific IgE wasp > 0.7 kU/l
-Age between 18-65 years old
-Patients shall give a written informed consent

Exclusion criteria

-Atopy (defined as positive Phadiatop)
-Severe asthma or emphysema, based on questionnaire; use of inhaled corticosteroids
-Symptomatic coronary heart diseases or severe (even under treatment) arterial hypertension
-Diseases with a contra-indication for the use of adrenaline
-Severe Kidney disease
-Treatment with β-blockers or immunosuppressive drugs
-Immunotherapy with venom ever or during the last 5 years with inhalant allergens
-Pregnancy, lactation or inadequate contraceptive measures
-Alcohol or Drug abuse
-Lack of co-operation or severe psychological disorders
-Systemic mastocytosis

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2007
Enrollment:	20

Type:	Anticipated

Ethics review

Approved WMO	
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	NL20270.042.07