Analyse van genetische expressie in bij en wesp allergie

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Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Allergische aandoeningen
Onderzoekstype	Observationeel onderzoek, met invasieve metingen

Samenvatting

ID

NL-OMON33607

Bron
ToetsingOnline

Verkorte titel
Genetische expressie in bij en wesp allergie

Aandoening

- Allergische aandoeningen

Synoniemen aandoening
bij en wesp allergie, Hymenoptera allergie

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Universitair Medisch Centrum Groningen
Overige ondersteuning: Ministerie van OC&W

Onderzoeksproduct en/of interventie

Trefwoord: bij en wesp allergie, Genetische expressie, immunotherapie

Uitkomstmaten

Primaire uitkomstmaten

The main parameter of the study is the gene expression profile which may

predict the long term effect of venom immunotherapy.

Secundaire uitkomstmaten

1. The secondary parameter is the gene expression profile which will be

specific for patients with the highest risk at a systemic reaction at a resting

* before insect venom immunotherapy?

2. The tertiary parameter is the gene expression profile specific for patients

with the lowest risk of the systemic reaction to insect sting at the end of

maintenance phase of VIT?

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Insect venom allergy (defined as at least one life systemic reaction in lifetime) is present in approximately 1-3% of population [1]. The treatment of choice in insect venom allergy (IVA) patients is immunotherapy with purified insect venom (VIT). Before treatment the risk at a systemic reaction to a subsequent sting is 70% and will be reduced to 3% after reaching maintenance dose [5]. After stopping VIT the risk at a re-systemic reaction increases in some patients with time, in others it remains low. Unfortunately it is not possible to predict long term efficacy in the individual patient so far.

Doel van het onderzoek

Objective of the study is to compare the gene expression profiles of patients who experienced a re-systemic reaction at a re-sting in spite of completing venom immunotherapy with patients who did not react at a re-sting after stopping VIT. The additional aim is to compare changes in gene expression before and after VIT.

Onderzoeksopzet

Comparison of differences in gene expression profiles between patients with different risk profiles.

Inschatting van belasting en risico

The proposed study has no risks for the health of investigated individuals.
The burden for patients in group 1 and 2 is related to the unscheduled visit in the outpatient department; therefore travel cost compensation is planned.
The burden for patients in group 3 and 4 is minimal because the blood samples will be taken as a routine procedure.
The benefit for patients is different with respect to the different patient groups. Subjects with a reaction after re-sting may prolong the immunotherapy or increase the dose of allergen used to gain better protection from systemic reactions after resting.
Remaining subjects will be informed about the results of the gene expression profile.
The results of the study might be important for the assessment of the risk of insect sting anaphylaxis and to advice on preventive methods to the individual patients.

Contactpersonen

Publiek

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Nederland

Wetenschappelijk

Universitair Medisch Centrum Groningen

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Nederland

Locaties

Landen waar het onderzoek wordt uitgevoerd

Netherlands

Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

see in english

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

see in english

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, met invasieve metingen

Blindering:	Open / niet geblindeerd
Controle:	Geen controle groep
Doel:	Algemeen wetenschappelijk

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	20-01-2009
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Ethische beoordeling

Goedgekeurd WMO

Soort:	Eerste indiening
Toetsingscommissie:	METC Universitair Medisch Centrum Groningen (Groningen)

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
CCMO	NL26199.042.08