RESolutie van Ontsteking in de Luchtwegen na Virale Expositie.

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We hypothesize that allergic asthmatics are less capable in resolving inflammatory cells after viral airway infection as a consequences of impaired expression of indoleamine 2,3-dioxygenase.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22107

Bron
NTR

Verkorte titel
RESOLVE

Aandoening

Virus-induced exacerbations in allergic asthmatics.

keywords: rhinovirus, exacerbation, allergy, asthma

Ondersteuning

Primaire sponsor: Department of Pulmonology of the Academic Medical Center in Amsterdam
Overige ondersteuning: Netherlands Asthma Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Common cold questionnaire;
2. Asthma symptom score;
3. FEV1;
4. PC20 methacholine;
5. Inflammatory cell numbers;
6. Indoleamine 2,3-dioxygenase expression;
7. Apoptotic markers.

Toelichting onderzoek

Achtergrond van het onderzoek

To investigate whether allergic asthmatics have an impaired capability to resolve inflammatory cells after viral airway infection, we will expose healthy individuals and allergic asthmatics to rhinovirus type 16. Volunteers will undergo two bronchoscopies to collect material before and after infection. In addition, lung function testing and asthma and common cold questionnaires will be included.

Doel van het onderzoek

We hypothesize that allergic asthmatics are less capable in resolving inflammatory cells after viral airway infection as a consequences of impaired expression of indoleamine 2,3-dioxygenase.

Onderzoeksopzet

1. 2 days prior to infection;

2. 4 days after infection (lung function testing only);

3. 6 days after infection.

Onderzoeksproduct en/of interventie

Healthy volunteers and allergic asthma patients will be infected by rhinovirus-type 16 (10 TCID50) by spraying the virus into the nasal cavity, leading to mild common cold symptoms. In general, these symptoms will be more pronounced for allergic astmatics and will be scored daily by the volunteers (through a modified asthma control questionnaire (ACQ) and a common cold questionnaire (CCQ)). We expect that the increased symptoms scores in asthmatics is associated with enhanced inflammation of the airways. We will therefore include several inflammatory markers in our study. We used cytokine levels in bronchoalveolar lavage fluid to calculate the power of the study. In this study we are trying to correlate symptoms, inflammation, viral load and relevant biomarkers of IDO-mediated tryptophan degradation in blood and lavage fluid. We will also include non-invasive

techniques to measure these end-points through NO measurements and exhaled breath condensate.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Allergic asthmatics:

1. Age between 18 and 40 yrs;

2. PC20 to methacholine below 8 mg/ml;

3. Skin-prick test positive to a least one common allergen.

Healthy:

1. Age between 18 and 40 yrs;

2. PC20 to methacholine above 16 mg/ml;

3. Skin-prick test negative to all common allergens.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Allergic asthmatics:

1. Current smokers;

2. Ex-smokers with more than 5 packyears;

3. Pre-FEV1 below 80% predicted;

4. Oral or inhaled steroid use;

5. Exacerbations during the past 6 weeks;

6. Underlying pulmonary condition other than asthma;

7. Non-pulmonary underlying conditions that may interfere with the study or that may result in unacceptable risk for the patient (incl. pregnancy);

8. Concomittant drug use (except short-acting bronchodilators);

9. Daily contact with young children (<2yrs).

Healthy:

1. Current smokers;

2. Ex-smokers with more than 5 packyears;

3. Pre-FEV1 below 80% predicted;

4. Oral or inhaled steroid use;

5. Underlying pulmonary condition other than asthma;

6. Non-pulmonary underlying conditions that may interfere with the study or that may result in unacceptable risk for the patient (incl. pregnancy);

7. Concomittant drug use (except short-acting bronchodilators);

8. Daily contact with young children (<2yrs).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2009
Aantal proefpersonen:	42
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	20-02-2009
Soort:	Eerste indiening

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
NTR-new	NL1597
NTR-old	NTR1677
Ander register	NAF 3-2-07-012 : 08/56
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A