RESolutie van Ontsteking in de Luchtwegen na Virale Expositie.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22107

Source
NTR

Brief title
RESOLVE

Health condition

Virus-induced exacerbations in allergic asthmatics.

keywords: rhinovirus, exacerbation, allergy, asthma

Sponsors and support

Primary sponsor: Department of Pulmonology of the Academic Medical Center in Amsterdam
Source(s) of monetary or material Support: Netherlands Asthma Foundation

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. Exhaled NO;

2. ENose measurement;

3. Coagulation parameters.

Study description

Background summary

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.

Study objective

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.

Study design

1. 2 days prior to infection;

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

3. 6 days after infection.

Intervention

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.

Contacts

Public
Dept. Pulmonology, F5-259
Academic Medical Center
University of Amsterdam
P.O. Box 22700

Peter J. Sterk
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5668137 or +31 (0)20 5664356
Scientific
Dept. Pulmonology, F5-259
Academic Medical Center
University of Amsterdam
P.O. Box 22700

Peter J. Sterk
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5668137 or +31 (0)20 5664356

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2009
Enrollment:	42
Type:	Actual

Ethics review

Positive opinion

Date:	20-02-2009
Application type:	First submission

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

Study results

Summary results
N/A