Pilot study: Biomarkers for diagnosis of neutrophil inflammatory/ allergic asthma

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

Summary

ID

NL-OMON43341

Source
ToetsingOnline

Brief title
Pilot study: Biomarkers for neutrophil inflammatory/ allergic asthma

Condition

- Allergic conditions

Synonym
(Severe) asthma

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: - Vriendenfonds Rijnstate - Wageningen Universiteit

Intervention

Keyword: Biomarkers, Neutrophils, Severe asthma

Outcome measures

Primary outcome

Th1/Th2/Th17 patterns in the nasal lavage, saliva and blood of healthy controls

by measuring cytokine levels.

Secondary outcome

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Study description

Background summary

About 10% of all asthmatics have severe, instable asthma and are steroid-resistant. Severe, instable asthma is associated with neutrophil recruitment and T helper (Th) 17 chemokine overexpression in bronchial biopsies. Phenotyping of patients is important to optimize therapy and disease outcome in an early stage. In clinical practise, for patients with severe asthma who show an inadequate response to standard therapy, treatment with macrolide antibiotics is considered.
In the Netherlands, asthma affects up to 3.5% of the adults and 4% of the children below the age of 15 yrs. In 2007 the overall health expenditure was ¤ 300 million. Half of these costs involve medication, i.e. combination preparations (a long-acting-sympathomimetic agent with inhaled corticosteroids). The annual direct medical expenditures and indirect nonmedical costs range from around ¤500 for stable asthma to ¤2281 for unstable asthma. Since unstable asthma burdens on overall health costs, early phenotypic classification of severe asthma can guide the choice of the most appropriate therapy with a reduction of exacerbations and health costs. However, at this moment routine non-invasive diagnostic tests for severe neutrophil inflammatory asthma are not available.

Study objective

The aim of this pilot study is to establish Th1/Th2/Th17 patterns in healthy controls by analysing cytokine concentrations in nasal fluid (nasal wash and cotton wool method), saliva and blood. This will be done in order to give an

estimation about the expected values in a healthy population and the biological variability of cytokines involved in the Th1/Th2/Th17 route. Furthermore it will give information about the correlation in these patterns between nasal fluid, saliva and blood.
Results of this pilot study will be used to start the main project; i.e. to validate these potential biomarkers for the diagnosis of neutrophil allergic asthma by measuring these analytes in patients suffering from severe, instable, neutrophilic, allergic asthma and eosinophilic asthma. The METC application for this main project will be send in at a later point in time.

Study design

Blood, saliva and nasal lavage of healthy subjects will be collected. Th1/Th2/Th17 patterns in these fluids will be determined measuring cytokine levels by flowcytometry.

Study burden and risks

Sampling will take place according to standard procedures of nasal fluid, saliva and blood sampling. Risks of participation include the regular risks involved in the sampling procedures; i.e. pain and bruises (for blood sampling), irritation and a dry feeling in the nose (for the collection of nasal fluid).

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

Healthy controls

Exclusion criteria

-People with asthma
-People suffering form other (chronic, pulmonary or autoimmune) diseases than asthma
-People that had an infection within two weeks prior to investigation
-People having immunodeficiency
-People who take steroids, antibiotics or probiotics

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	02-06-2016
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	05-04-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL56960.091.16