The expression of inhibitory receptors on leukocytes in allergic rhinitis. (EXIRA-study)

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To compare the expression of inhibitory receptors on immune competent cells in the airways of patients with allergic rhinitis, patients with infectious rhinitis. A secondary aim is to determine the relationship between inhibitory receptor expression...

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

Summary

ID

NL-OMON36104

Source
ToetsingOnline

Brief title
EXIRA

Condition

- Allergic conditions

Synonym
allergic rhinitis, hay fever

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: allergic rhinitis, LAIR-1, leukocytes, receptor

Outcome measures

Primary outcome

(1) Expression of inhibitory receptors (LAIR-1, SIRL-1, CD200R, CTLA-4 en

SIRP-α) on leukocytes in peripheral blood and nasopharyngeal washes (2) Changes

in inhibitory receptor expression in nasopharyngeal washes during the course of

disease.

Secondary outcome

-Flow cytometry of will be used to study inhibitory receptor expression during

the course of disease

Study description

Background summary

Allergic rhinitis is a common chronic disorder in children and adults. Although the signs and symptoms may be mild, the economic burden is high. The pathogenesis is extensively studied, but not yet completely understood. It has been suggested that an imbalance in immune regulation plays an important role. The hypothesis of this study is that allergic rhinitis is associated with decreased expression of inhibitory receptors. Our research group has special interest in inhibitory receptor leukocyte-associated immunoglobulin-like receptor 1 (LAIR-1).

Study objective

To compare the expression of inhibitory receptors on immune competent cells in the airways of patients with allergic rhinitis, patients with infectious rhinitis. A secondary aim is to determine the relationship between inhibitory receptor expression and disease severity during the course of disease.

Study design

Observational case-control study

Study burden and risks

Due to the type of study, observational, with invasive diagnostic procedures as previously described, but no adverse or serious adverse events are to be expected.
-Venous blood (10 ml) will be drawn from all patients by venapuncture.
-Nasopharyngeal wash is a non-invasive technique where mucus is suctioned from the nose. The burden for the patient is low. Researchers are experienced with this technique. No complications have been described.

Discomfort caused by nasal sampling will be monitored in 7 patients with allergic rhinitis and 7 patients with infectious rhinitis by one independent research nurse or other researcher in the hospital using an 10-point visual analogue scale. Discomfort will be scored during every sample collection at 3 timepoints: before collection of the aspirate, during aspiration and 5 minutes after the procedure.

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

Patients with allergic rhinitis
-Age 18-35 years
-No severe co-morbidity, other than allergic symptoms
-Proven allergic rhinitis (based on clinical evaluation of a medical doctor or with positive RAST) experiencing at least nasal symptoms
-Suffering from outdoor allergies (hay fever, pollen, weeds, grass) or indoor allergies (mold, dust, dust mite) or pet allergies.
- Good understanding of the Dutch language
- Willingness to receive a member of the investigation team in the house of the participant;Controls
-Healthy individuals 18-35 years with a runny nose

Exclusion criteria

-Any severe comorbidity
-Any other infection during the department visit
-Immunological nasal disease (Churg-Strauss syndrome, Sjögren*s syndrome, systemic lupus erythematosus, sarcoidosis, Wegener*s granulomatosis)
-Use of nasal corticosteroid spray 1 month or less prior during the hospital visit.
-Use of oral corticosteroids 1 month or less prior during the hospital visit.

Study design

Design

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

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-01-2012
Enrollment:	84
Type:	Actual

Ethics review

Approved WMO

Date:	02-11-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL37135.041.11