The effect of nasal provocation on clinical response and nasal inflammatory parameters in nonallergic rhinitis, mixed rhinitis and allergic rhinitis patients versus healthy individuals

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Ethical review	Approved WMO
Status	Pending
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Interventional

Summary

ID

NL-OMON32628

Source
ToetsingOnline

Brief title
Nonallergic rhinitis

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
non-allergic rhinitis and non-allergic nasal complaints

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Clinical response, Epithelial expression, Nasal provocation, Nonallergic rhinitis

Outcome measures

Primary outcome

1. The difference between clinical and local inflammatory reaction to non-specific stimuli in nasal provocation tests in nonallergic rhinitis patients, mixed rhinitis patients, perennial allergic patients and healthy individuals

2. The difference in reaction between nonallergic rhinitis patients, mixed rhinitis patients, perennial allergic patients and healthy individuals to nasal provocation tests

3. The difference in reaction between chemical and physical non-specific stimuli and airborne allergen in nasal provocation tests in nonallergic rhinitis patients, mixed rhinitis patients, perennial allergic rhinitis patients and healthy individuals.

4. The differences between the genetic expression profile of rhinitis at RNA level in nonallergic rhinitis, mixed rhinitis, allergic rhinitis patients and healthy individuals using the Affymetrix micro-array technology

Secondary outcome

not applicable

Study description

Background summary

Chronic rhinitis is a common disorder, that can have great impact on quality of life of patients. The pathophysiology can be divided into several subgroups. Beside infectious and allergic rhinitis, nonallergic rhinitis forms an important entity within rhinitis. Patients have symptoms that mimic allergic rhinitis, such as rhinorrhea, nasal blockage and sneezing, of which the definite pathophysiology has not been decribed. The diagnosis is largely based on exclusion criteria. It has been suggested that the pathophysiologic or pathogenic origin of nonallergic rhinitis has its origin at RNA level. Since the nasal symptoms mimic those of allergic rhinitis, but triggering agents of the symptoms differ largely, an adequate comparison between these groups, would give better insight into the pathophysiology of nonallergic rhinitis. Characterization of the phenotype of nonallergic rhinitis would help to better understand the pathophysiology, diagnosis and management.

Study objective

By a chemical, physiological and IgE-mediated nasal provocation test, nasal responses will be provoked in different patientgroups. The clinical response will be measured by visual analogue score, rhinitis symptomscore, peak nasal inspiratory flowmetry and nasal nitric oxide measurement. The local response will be measured by the quantification of mediators of inflammation in the nasal secretion. Based on these responses, phenotypes of the different subgroups. will be defined.
At RNA-level a baseline genetic expression profile of the epithelium for mediators of inflammation and rhinitis will be determined by micro-array technology.
We will compare patients from the nonallergic rhinitis subgroup to allergic rhinitis patients, mixed rhinitis patients and healthy subjects.

Study design

This will be an observational study with cross-over design. All subjects will visit the ear-, nose- throat department at 4 occasions. The first visit will be a screening visit with baseline measurements and the nasal biopsyprocedure. Then the three provocationvisits will take place in random order. Each provocation will be done with a different nasal trigger. The agents that will be used as a nasal trigger are nasal capsaicinspray, cold dry air and housedustmiteextract. On various timepoints after provocation, clinical reaction and local nasal inflammatory reaction will be determined by VAS score, nasal symptom score, peak nasal inspiratory flow measurement, nasal NO

measurement and nasal secretion.

Intervention

The four studygroups will undergo equal interventions. During the provocationvisits, nasal provocations will take place with three different entities. The provocation with capsaicin nasal spray will be performed in 4 increasing dosages: placebo, 0.5 microgram, 5.0 microgram and 10.0 microgram. The cold dry air provocation will be performed in the next increasing dosages: 12.5 L, 25 L, 50 L, 100 L, 200 L and 400 L. The provocation with housedustmite will be performed, using the following increasing dosages of Der-P-1 housedustmite extraction in aqueous solution: Placebo, 100 BU, 1000 BU and 10.000 BU

Study burden and risks

Patients with rhinitis cease the use of their nasal medication within one month before participation. 48 Hours before each studyvisit, they do not take antihistamines. There is a chance of a considerable increase of their rhinitis symptoms. If abstinence from their medication is not possible, subjects cannot be included in this study.
Subjects visit the ENT-department at four occasions of approximately 2 hours each. In 40 subjects, nasal biopsies will be taken. The complication of nasal biopsies is epistaxis.The incidence of epistaxis after nasal biopsies is reported as being less than 5% and of moderate severity. In case epistaxis occurs, treatment will consist of local application of Xylometzoline 0.01%, or if necessary, a dissolvable nasal tampon will be placed. There will not be a definitive change of the nasal mucosa after biopsy; complete healing will occur.

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

male or female between 18 to 68 years of age inclusive
capable of giving written informed consent

Exclusion criteria

Use of nasal corticosteroids within 4 weeks before participation and during study
Nasal conditions likely to effect the outcome of the study, i.e. nasal malformations
Use of intranasal medication to treat nasal symptoms
Nasal or sinussurgery in the previous three months
Use of antihistamines in the 48 hours before each visit
Recent upper airway infection
Serious or unstable co-morbidity
A diagnosis of asthma
Pregnant or lactating females
Past medical history of nasal polyposis
Smoking
Inability to follow the instructions or completing all studyprocedures

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2009
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL25750.018.08