Nasal hyperreactivity after short-time cold dry air provocation in chronic rhinitis patients.

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

Summary

ID

NL-OMON37734

Source
ToetsingOnline

Brief title
Short Cold Dry Air Provocation

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
nasal hypersenstivitiy, vasomotor rhinitis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Allergic rhinitis, Clinical symptoms, Nasal hyperreactivity, Nonallergic rhinitis, Short Cold Dry Air nasal provocation, Vasomotor rhinitis

Outcome measures

Primary outcome

Clinical outcomes (symptomscore and nasal flow):

Symptomscore

The patient will be asked 1 minute before and 1 minute after provocation to assess the degree of their nasal symptoms by completing a 100 mm Visual Analogue Scale (VAS) and a Rhinitis Symptom Score (RSS). An example of the 100 mm visual analogue scale is illustrated below:

No symptoms

Worst possible symptoms

The patients will also be asked to complete a rhinitis symptom score (RSS) for the following symptoms: rhinorrhoea, nasal blockage, sneezing, itching in the nose and burning in the nose.

Symptom score None (0) Mild (1) Severe (2)

Rhinorrhea

Blockage

Sneezing

Itching in nose

Burning in nose

Nasal Flow:

Peak Nasal Inspiratory Flow Rate (PNIF):

An "InCheck" peak nasal inspiratory flow meter is used to derive forced

inspiratory peak flow through the nose. Three maximal inspiratory efforts will

be made and the highest value recorded. PNIF will be measured one minute

before and minute after provocation.

Secondary outcome

not applicable

Study description

Background summary

Chronic rhinitis is a common disorder, that can have a great impact on quality of life of patients.
The pathofysiology of chronic rhinitis is not completely understood. Especially the role and definition of nasal hyperreactivity in the different types of

chronic rhinitis patients stays unclear. Hypotheses state that nasal hyperreactivity could be a neurologic disorder or a disbalance of the sympathic and parasympathic neurologic systems, a symptom with an inflammatoiry background or even a hidden local allergy of the nasal mucosa.
For a long time nasal hyperreactivity was mainly correlated with non-allergic rhinitis patients, but recent evidence shows that also allergic rhinitis patients can have symptoms of nasal hyperreactivity, apart from their IgE mediated allergy symptoms.

Study objective

The clinical response will be measured in allergic and non-allergic rhinitis patients and healthy participants. This will be done by means of symptom scores: visual analogue score (VAS) and rhinitis symptome score (RSS) and by means of measuring nasal patency and flow: peak nasal inspiratory flowmetry (PNIF).

Study design

Three groups of 30 participants, ie. 30 allergic rhinitis patients, 30 non-allergic rhinitis patients and 30 healthy controles will be included. Participants will be recruted from previous studies of the ENT AMC Research Departments (like the NAR study), but also from the population of (chronic) rhinitis patients visiting the ENT outpatient clinic or the ENT research department during the previous years and who all received a documented allergy test (skin prick test).
To be included in our study allergy will be (again) investigated by means of a skin prick test according to GA2LEN standards with the 18 most common inhalation allergens. In non-allergic rhinitis patients and healthy controls results of skin prick testing have to be completely negative apart from the positive control. In allergic rhinitis patients apart from the positive control at least one other positive result has to come up.
Chronic rhinitis patients have to have for at least 1 year symptoms of the nose, ie at least one of the following symptoms: rhinorrhoea (runny nose), nasal congestion (blocked nose), itchy nose, sneezing or burning/painful sensation in the nose. These symptoms have to be at least troublesome for the patient.
Patients have to stop local (or systemic) corticosteroids 4 weeks before their visit, and antihistamines (spray or tablet) 3 days before their visit.
The visit will include a screening and allergy investigation (skin prick test). (60 minutes) During this screening visit demographic features and symptoms of rhinitis, medicale history and medication use -as applicable- will be documented and an ENT and a short general physical examination will be performed.
Than provocation with cold dry air will take place. (20 minutes) One minute before provocation patients will fill in a Visual Analogue Scale (VAS) for 5

different nasal symptoms. (rhinorrhoea, nasal congestion, itchy nose, sneezing, burning/pain) and a Rhinitis Symptom Score (RSS) for the same 5 symptoms. Also a Peak Nasal Inspiratoiry Flow Measurement (PNIF) will be performed to assess nasal patency.
After this screening part a provocation of 15 minutes breathing of cold dry air of at least minus 10 degrees Celcius with a flow of 25 L/minute through the nose with a nasal silicon mask will take place, as described by Braat etal in 1997. At one minute after ending 15 minutes provocation, patients will again fill in the VAS scores and RSS scores and perform another Peak Nasal Inspiratory Flow Measurement (PNIF).
After these measurements the visit will be ended.

Intervention

All groups will undergo a nasal provocation with dry cold air for 15 minutes.

Study burden and risks

Patients with rhinitis stop the use of their nasal medication within one month before participation. Antihistamines will not be taken 48 hour before the visit. 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.
All participants visite the ENT- Research Department during two hours, in which skinprick test, screening and nasal provocation will be performed.

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 18-68 years of age inclusive capable of giving written informed consent

Exclusion criteria

Use of nasal corticosteroids within 4 weeks before participation
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:	Recruitment stopped
Start date (anticipated):	20-01-2012
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	23-04-2012
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	NL39904.018.12