Bronchial and nasal and hyperreactivity in chronic (non-) allergic rhinitis

Published: 31-07-2020
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Primary Objective: • To determine the prevalence of NHR and BHR and determine the relationship between them in patients with chronic allergic and non-allergic rhinitis and compare with controls.Secondary Objective(s): • To determine differences in...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Observational non invasive

Summary

ID

NL-OMON52412

Source
ToetsingOnline

Brief title
BANA(H)NA

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
blocked nose, Chronic rhinitis, running nose

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, hyperreactivity, non-allergic rhinitis

Outcome measures

Primary outcome

The prevalence of NHR and BHR and the relationship between them in patients with chronic allergic and non-allergic rhinitis. Comparison with prevalence of NHR and BHR in the control group.

Secondary outcome

• The difference in the prevalence of NHR and BHR in patients with chronic allergic and non-allergic rhinitis and controls.

• CDA reactivity in patients with chronic allergic and non-allergic rhinitis and controls.

• Histamine Challange Test reactivity in patients with chronic allergic and non-allergic rhinitis and controls.

Study description

Background summary

Nasal (NHR) and bronchial (BHR) hyperreactivity are common features of chronic allergic and non-allergic rhinitis. The nature of evoking triggers is often unclear and also there are very little data about the correlation between symptoms of both NHR and BHR and objective measurements of hyperreactivity in these diseases.

Study objective

Primary Objective:
• To determine the prevalence of NHR and BHR and determine the relationship between them in patients with chronic allergic and non-allergic rhinitis and compare with controls.

Secondary Objective(s):
• To determine differences in NHR and BHR in patients with chronic allergic and non-allergic rhinitis and controls.
• To measure CDA reactivity in patients with chronic allergic and non-allergic rhinitis and controls.
• To measure Histamine Challange Test reactivity in patients with chronic allergic and non-allergic rhinitis and controls.

Study design

Observational cohort study in patients visiting the department of otorhinolaryngology of the Amsterdam University Medical Centres, location AMC. The control group will consist of healthy volunteers (no asthma/chronic rhinitis/chronic rhinosinusitis) that are willing to participate in the study.

Study burden and risks

Bronichial Histmaine Challange Test - one occasion
Nasal Cold Dry Air Provocation - one occasion

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Inclusion criteria for all groups
Adults 18-70 years of age
2. Inclusion criteria per group
2.1 Chronic allergic rhinitis
- Symptoms of rhinitis: rhinorrhoea/ nasal blockage/ sneezing/ itchy nose for at lease 1 hour daily for a minimum of 12 weeks per year.
- No signs of chronic rhinosinusitis (CRS) on nasal endoscopy (i.e. nasal polyps, mucopurulent discharge primarily from the middle meatus, oedema/mucosal obstruction primarily in the middle meatus) or computerized tomography scan (i.e. mucosal changes in the ostiomeatal complex and/or sinuses).
- Positive for inhalational allergens test (skin-prick test, Phadiatop) with clinically relevant sensitization in the last two years.
2.2 Chronic non-allergic rhinitis
- Symptoms of rhinitis: rhinorrhoea/ nasal blockage/ sneezing/ itchy nose for at lease 1 hour daily for a minimum of 12 weeks per year.
- No signs of CRS on nasal endoscopy (i.e. nasal polyps, mucopurulent discharge primarily from the middle meatus, oedema/mucosal obstruction primarily in the middle meatus) or computerized tomography scan (i.e. mucosal changes in the ostiomeatal complex and/or sinuses).
- Negative allergy test (skin-prick test, Phadiatop) in the last two years.
2.3 Controls
- No symptoms of rhinitis/rhinosinusitis like rhinorrhorea, nasal blockage, itch, sneezing, facial pain, post nasal drip and loss of smell;
- No middle ear pathology;
- No asthma.
- Normal lung function (FEV1 >80% of predicted and FEV1/FVC ratio >0.75).
- Negative allergy test (skin-prick test).
- FeNO < 25 ppb.
- PC20 to histamine > 8 mg/ml

Exclusion criteria

1) Acute upper or lower respiratory tract infection within 3 weeks before the inclusion visit;
2) Chronic rhinosinusitis;

3) Systemic diseases affecting the nose (e.g., Wegener*s, granulomatosis, sarcoid, primary ciliary dyskinesia, cystic fibrosis);
4) Inverted papilloma or malignant tumours of the sinonasal region;
5) Nasal/sinus surgery in the last 3 months;
6) Skin prick test or serum IgE measurement older than 2 years;
7) The presence of nasal mucosal erosion, nasal ulceration, or nasal septal perforation;
8) A known history of alcohol or drug abuse within the last 2 years;
9) Recreational drug use in the past 72 hours;
10) Existence of any surgical or medical condition or physical or laboratory findings, which in the opinion of the investigator, might significantly affect the patient*s ability to complete this trial; or their safety in this trial;
11) Smoking (including participants who stopped smoking <6 months pre-testing or participants who stopped smoking >6 months ago but smoked more than 5 packyears);
12) Exposed to passive smoking in the past 72 hours;
13) BMI > 30;
14) Topical nasal decongestant abuse;
15) Severe septal deviation, nasal valve dysfunction;
16) Pregnancy and nursing;
17) Medication affecting nasal function (e.g., β-blockers);
18) Subjects unable to stop using medication presented in Table 3 within the corresponding timeframes;
19) Subjects unable to withdraw the use of medication presented in Attachment 1 with corresponding time periods before HBPT;
20) FEV1 < 60% predicted or 1.5 L;
21) Inability to perform acceptable and repeatable spirometry manoeuvres throughout the test procedure;
22) Myocardial infarction or stroke in last 3 months;
23) Uncontrolled hypertension (BP systolic > 200 mmHg, diastolic > 100 mmHg);
24) Known aortic aneurysm;
25) Recent eye surgery or intracranial pressure elevation risk;
26) Inability to perform any of the testing manoeuvres, such as inhaling the challenge agent consistently;
27) Use of cholinesterase inhibitor medication (e.g. for myasthenia gravis): neostigmine, pyridostigmine
28) A positive COVID-19 self-test (within maximum of 48 hours prior to bronchial provocation).
29) Any other physical or psychological factors precluding subjects of participation in this protocol (either safety, compliance-wise) or as deemed by the investigator.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-10-2021
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO Date:	31-07-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-07-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-01-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-06-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214

Postbus 22660

1100 DD Amsterdam

020 566 7389

mecamc@amsterdamumc.nl

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	NL72186.018.20