

Visualisation of the microcirculation of the nasal mucosa in vivo in different nasal disorders, using sidestream dark-field imaging

Submission date 21/07/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 21/07/2006	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 05/11/2008	Condition category Ear, Nose and Throat	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

NTR719

Study information

Scientific Title

Acronym

ViMiNa

Study objectives

Xylometazoline nasal spray relieves vasoconstriction in the nasal mucosa, which will be assessed and visualised using sidestream dark-field (SDF) imaging.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Nasal disorder

Interventions

The microcirculation of the nasal mucosa of healthy controls will be assessed using a non-invasive probe, diameter 0.5 cm, which will be placed in the nasal cavity, twice for a period of approximately 10 minutes. Images will be recorded to make off-line analysis possible. In between the two periods of recording or measuring, the healthy volunteers will get a provocation with xylometazoline nasal spray or placebo. After a few minutes, a second measurement will be taken to assess possible differences in the microcirculation.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Xylometazoline

Primary outcome(s)

The following parameters will be used to assess the microcirculatory reaction after provocation: Flow in the capillary, venules and arterioles can be scored semi-quantitatively or quantitatively:

1. Semi-quantitative scoring:

0 = no flow

1 = intermittent flow

2 = sluggish flow

3 = continuous flow

2. Quantitative scoring: velocity, flow, diameter, length, density

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/12/2006

Eligibility

Key inclusion criteria

1. Patients with active allergic rhinitis, idiopathic rhinitis, chronic rhinosinusitis or nasal polyps
2. Males or females aged over 18 years; no maximum age
3. Approval from the patient's physician
4. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Smoker
2. Severe cardiac or pulmonary disorder
3. Peripheral vascular disease
4. Medication: systemic alpha-blockers, corticosteroids (local and systemic), any local nasal treatment, bronchodilatory inhalation medication for pulmonary diseases >1000 µg/day
5. Cystic fibrosis, immotile cilia syndrome, Rendu-Osler-Weber disease, vasculitis
6. Cocaine and/or alcohol abuse

Date of first enrolment

01/07/2006

Date of final enrolment

01/12/2006

Locations

Countries of recruitment

Netherlands

Study participating centre
Academic Medical Centre (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

ROR
<https://ror.org/03t4gr691>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration