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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 21/07/2006	**Overall study status** Completed	
Last Edited 05/11/2008	**Condition category** Ear, Nose and Throat	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/07/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

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)

Sponsor details
Department of Otorhinolaryngology
P.O. Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl

ROR

https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration