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

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

#### Plain English summary of protocol

Not provided at time of registration

# **Contact information**

**Type(s)** Scientific

**Contact name** Prof W J Fokkens

#### Contact details

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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 noninvasive 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

**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