Visualization of the microcirculation of the nasal mucosa in vivo in different nasal disorders, using Sidestream Dark-Field (SDF) imaging.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24686

Source
NTR

Brief title
ViMiNa

Health condition

20 healthy volunteers will be exposed to either provocation with xylometazoline nasal spray or placebo.

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam.
Department of Otolaryngology and Clinical Physiology
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

The following parameters will be used to asses 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 and 3 = continuous flow);

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

Secondary outcome

N/A

Study description

Background summary

The nose, and in particular the nasal mucosa, is a very dynamic organ system. It combines olfactory and respiratory functions and acts as a first defence mechanism against pathogens. The nose maintains a rich neurovascular network to manage the different tasks of which the nasal microcirculation stands out in managing these very diverse physiological processes. However, little is known about abnormalities of the microcirculation and the role it may play in different nasal dysfunctions or disorders.

In this study we would like to assess the microcirculation of healthy subjects as well as to observe the expected of a widely used nasal spay: xylometazoline.
This over-the-counter availabele nasal spray works as a decongestent and is widely used.

As a sympathicomimeticum its main effect is vasocontriction. The aim is to visualize this reaction in healthy subjects using a double blind placebo controlled setting.

Study objective

Xylometazoline nasal spray realizes vasoconstricion in the nasal mucosa, which will be assessed and visualized using SDF imaging.

Study design

N/A

Intervention

The microcirculation of the nasal mucosa of healthy controls will 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/measuring, the healthy volunteers will get a provocation with xylometazoline nasal spray or placebo. After a few minutes the second measurement will be done to assess the possible differences in the microcirculation.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with active allergic rhinitis, idiopathic rhinitis, chronic rhinosinusitis or nasal polyps;

2. Males or females aged over 18 years with no maximum age;

3. Approval of the patient’s physician;

4. Written informed consent.

Exclusion criteria

1. Smoking;

2. Severe cardiac or pulmonary disorder;

3. Peripheral vascular disease;

4. Medication:

systemic: â blockers, corticosteroids (local and systemic);

any local nasal treatment;

bronchodilatory inhalation medication for pulmonary diseases > 1000 ìg/day;

5. Cystic fibrosis, Immotile cilia syndrome, Rendu-Osler-Weber disease, vasculitis;

6. Cocaine and/or alcohol abuse.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2006
Enrollment:	20
Type:	Actual

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL710
NTR-old	NTR719
Other	: N/A
ISRCTN	ISRCTN67264420

Study results

Summary results
N/A