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

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

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24686

Bron
NTR

Verkorte titel
ViMiNa

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam.
Department of Otolaryngology and Clinical Physiology
Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2006
Aantal proefpersonen:	20

Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL710
NTR-old	NTR719
Ander register	: N/A
ISRCTN	ISRCTN67264420

Resultaten

Samenvatting resultaten
N/A