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

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To assess the normal nasal microcirculation in vivo. Also, this research may lead to a better understanding of the pathophysological mechanisms operative in nasal dysfunction. It may help us to differentiate between aetiology of different disorders...

Ethical review	Approved WMO
Status	Pending
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Observational non invasive

Summary

ID

NL-OMON29716

Source ToetsingOnline

Brief title imaging of the nasal microcirculation

Condition

• Upper respiratory tract disorders (excl infections)

Synonym capillaries, microcirculation

Research involving Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: microcirculation, nose, SDF imaging

Outcome measures

Primary outcome

The following parameters will be used to asses the microcirculatory function in patients with allergic rhinitis, idiopathic rhinitis, chronic rhino sinusitis and nasal polyps:

Flow in the capillary, venules and arterioles can be scored semi quantitatively or quantitatively:

*Semi quantitative scoring:

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(0 = no flow, 1 = intermittent flow, 2 = sluggish flow and 3 = continuous flow)
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*Quantitative scoring:

velocity, flow, diameter, length, density

Secondary outcome

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

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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.

The most common disorder is the common cold, caused by a viral infection. Unlike this common cold, which is self-limiting, about 20% of the population suffers from chronic rhinitis. Chronic rhinitis can be divided into allergic rhinitis, infectious and non-allergic, non-infectious rhinitis. The latter is called idiopathic rhinitis and diagnosis is made by exclusion of specific causes such as, for example, medication usage, smoking or hormonal. Other chronic disorders in ENT medicine comprise chronic rhino sinusitis and nasal polyps; by some classified as belonging to the same range of disorders. The precise cause is still unknown and most patients present with a combination of the two disorders.

Often underestimated, but the above described, chronic disorders can impair quality of life in a great deal. It can contribute to sleep disorders, social or emotional problems, school or work functioning, and not to mention the financial consequences it has for society. Besides that, many patients respond differently, or do not respond at all to therapy. Because of the complexity of complex disorders, it is sometimes difficult to set the right diagnosis and therapy. It has been suggested that quantitative and qualitative differences in the nasal microvasculature may be detected amongst the above-described disorders.

Most of the methods used to study the microcirculation in nasal dysfunction rely on immunohistochemistry. Up until now, the methods used to visualize the microcirculation in vivo in nasal mucosa are laser Doppler flowmetry and rhinostereometry.

In the present study, the microcirculation of the nasal mucosa will be analysed with a relatively new technique, called SDF imaging (Microscan, Microvision Medical, Amsterdam), an improved version of OPS imaging. It is a hand held microscope, emitting green light, which can be used to observe the microcirculation in great detail. It has been used and is being used in a number of clinical studies in the AMC currently. With this technique, different factors of the microcirculation can be visualized and differences among groups can be compared. It is the first time that the microcirculation of nasal mucosa is visualized in vivo with SDF imaging. As such, we propose that this approach will lead to a better understanding of the pathophysological mechanisms operative in nasal dysfunction. It may help us to differentiate between aetiology of different disorders and may clear out why some people react well to medication while others do not (anymore).

Study objective

To assess the normal nasal microcirculation in vivo. Also, this research may lead to a better understanding of the pathophysological mechanisms operative in nasal dysfunction. It may help us to differentiate between aetiology of different disorders and may clear out why some people react well to medication while others do not (anymore).

Study design

single center pilot study

Study burden and risks

The technique used is non-invasive. The presence of the probe in the nasal cavity can give an inconvenient experience. If possible, this will be avoided. The usage of the SDF imaging device is harmless and this research has not impact on further treatment.

Contacts

Public Academisch Medisch Centrum

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

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Inclusion criteria

- Patients with active allergic rhinitis, idiopathic rhinitis, chronic rhinosinusitis or nasal polyps;
- Males or females aged over 18 years with no maximum age;
- Approval of the patient*s physician;
- Written informed consent;

Exclusion criteria

- Smoking;
- Severe cardiac or pulmonary disorder;
- Peripheral vascular disease;
- Medication:

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

any local nasal treatment;

bronchodilatory inhalation medication for pulmonary diseases

> 1000 *g/day;

- Cystic fibrosis, Immotile cilia syndrome, Rendu-Osler-Weber disease, vasculitis;
- Cocaine and/or alcohol abuse.

Study design

Design

Study type:	Observational non invasive	
Intervention model:	Other	
Allocation:	Non-randomized controlled trial	
Masking:	Open (masking not used)	
Control:	Active	
Primary purpose:	Basic science	

Recruitment

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Recruitment status:	Pending
Start date (anticipated):	01-07-2006
Enrollment:	60
Туре:	Anticipated

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Ethics review

Approved WMO Application type: Review commission:

First submission METC Amsterdam UMC

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 CCMO ID NL12354.018.06