Microvascular changes and microvascular reactivity in stable patients with Chronic Obstructive Pulmonary Disease using non-invasive retinal imaging

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26359

Source Nationaal Trial Register

Health condition

Chronic Obstructive Pulmonary Disease

Sponsors and support

Primary sponsor: VITO and CIRO Source(s) of monetary or material Support: VITO

Intervention

Outcome measures

Primary outcome

Presence of changes in the retinal microvasculature (for example change in vessel caliber, geometric pattern, etc) in patients with COPD.

Secondary outcome

-Endothelial function analyzed via reactive hyperemia, blood pressure and ankle brachial index in patients with COPD.

-The effect of a high-intensity exercise on the reactivity of the retinal microvasculature in patients with COPD compared to non-COPD subjects (obtained in an earlier study).

-The effect of an 8-week inpatient rehabilitation program on the retinal vessel calibers in patients with COPD.

-The association between 1) retinal vessel changes/retinal vascular reactivity and cardiovascular phenotyping (endothelial function, blood pressure, ankle brachial index, AFR), 2) retinal vessel changes/retinal vascular reactivity and relevant outcomes for COPD patients (e.g. lung function, CAT, 6MWT, CPET, CWRT, smoking status; all included in the routine baseline assessment prior to rehabilitation)

Study description

Background summary

Rationale: COPD is considered as a complex, heterogeneous, and multicomponent condition in which comorbidities are frequently present. Indeed, patients with COPD are more likely to be diagnosed with (risk factors for) cardiovascular disease. Smoking is the most important risk factor for the development of COPD and has negative effects on the airway epithelium, the endothelium and microvasculature in multiple organs. Retinal image analysis is an unobtrusive procedure for visualizing the microcirculation. Since similarities exist between retinal blood vessels and the microvasculature of the heart, lungs, and brain, retinal imaging can be used to identify diseases of the eye but also cardiovascular diseases and risk factors. To date, little is known about microvascular changes and the possible beneficial effect of physical activity in patients with COPD.

Objective: Part 1: to determine the presence of changes in the retinal microvasculature in patients with COPD; Part 2: to determine the effect of physical activity on the function of the retinal microvasculature.

Study design: Prospective observational study.

Study population: Clinically stable patients with COPD entering pulmonary rehabilitation at Ciro+ in Horn.

Intervention (if applicable): All COPD patients will participate in a regular comprehensive rehabilitation program at Ciro+. Retina photos will be taken during standard begin assessment and outcome assessment (part 1). In addition, 6 photos will be taken before and after a high-intensity exercise, which is part of the standard rehabilitation program (part 2).

Main study parameters/endpoints: The presence of changes in the retinal microvasculature in patients with COPD. The changes are quantified as changes in the diameter of the central retinal arteriolar equivalent and the central retinal venular equivalent.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: All interventions take place at Ciro+ in Horn as part of regular pulmonary rehabilitation. In addition, retina photos will be taken in participating patients. When taking the photo, patient will experience a flash of the camera. The possible inconvenience of this flash will disappear completely after a few seconds. It takes less than 5 minutes to take the retinal photo. The EndoPAT is completely safe and harmless, however, the 5 minutes occlusion of the brachial artery may cause some minor discomfort and tingling in the fingers. The risks of participation in the study are almost zero.

Study objective

Since cigarette smoke has effects on the airway epithelium, but also causes endothelial damage and loss of the microvasculature in multiple organs, it seems reasonable to assume that microvascular changes are more present in patients with COPD compared to healthy control subjects.

Since physical exercise has a positive effect on the structure and functionality of the blood vessels, it seems reasonable to assume that an 8-week pulmonary rehabilitation program has a beneficial effect on retinal microvascular status and endothelial function in patients with COPD.

Study design

Measurements will be performed before and after an 8-week pulmonary rehabilitation program.

Intervention

Before and after rehabilitation, microvascular changes and reactivity will be measured using retinal imaging and endothelial function will be analyzed via reactive hyperemia, blood pressure and ankle brachial index.

Contacts

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Eligibility criteria

Inclusion criteria

-COPD as a primary diagnosis according to the Global Initiative For Chronic Obstructive Lung Disease (GOLD) definition: "Chronic obstructive pulmonary disease (COPD) is a preventable and treatable disease with some significant extrapulmonary effects that may contribute to the severity in individual patients. Its pulmonary component is characterized by airflow limitation that is not fully reversible. The airflow limitation is usually progressive and associated with an abnormal inflammatory response of the lung to noxious particles or gases". COPD is diagnosed by a chest physician.

-Clinically stable on the basis of clinical picture by chest physician.

-Treated according to the current international guidelines.

-Permission for voluntary participation. Patients will be asked during baseline assessment and have to sign an informed consent. Patients have the right to withdraw from the study without any negative consequences on their rehabilitation.

-Attending the regular rehabilitation program in Ciro+

Exclusion criteria

-Lack of motivation for voluntary participation in this study.

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-The presence of abnormalities in the lens (e.g. cataract) or retina (e.g. retinal detachment), which makes it impossible to make an image of the retina.

-The presence of severe diabetic retinopathy, which makes it impossible to analyze the microvasculature of the retina.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

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NL	
Recruitment status:	Pending
Start date (anticipated):	21-06-2016
Enrollment:	246
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	14-06-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45747 Bron: ToetsingOnline

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Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5479
NTR-old	NTR5896
ССМО	NL56813.100.16
OMON	NL-OMON45747

Study results