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

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-To determine the presence of changes in the retinal microvasculature and endothelial function in patients with COPD (part 1) -To determine the effect of physical exercise on microvasculare reactivity in patients with COPD and the effect of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON45747

Source ToetsingOnline

Brief title Retinal imaging in COPD

Condition

• Bronchial disorders (excl neoplasms)

Synonym

chronic obstructive pulmonary disease; chronic lungdisease with persistent obstruction of the airways

Research involving

Human

Sponsors and support

Primary sponsor: Ciro+ Source(s) of monetary or material Support: VITO

Intervention

Keyword: Cardiovascular Diseases, Chronic Obstructive, Motor Activity, Pulmonary Disease, Retina

Outcome measures

Primary outcome

The presence of changes in the retinal microvasculature and endothelial

function in patients with COPD.

Secondary outcome

- The effect of a high-intensity exercise on the reactivity of the retinal

microvasculature in patients with COPD.

- The effect of an 8-week inpatient rehabilitation program on the function of

the retinal microvasculature and endothelial 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).

- Presence of ocular complications (i.e. glaucoma, age dependent macula degeneration), which are determined by an ophthalmologist.

Study description

Background summary

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 not only be used to identify diseases of the eye but also to identify cardiovascular diseases and risk factors. To date, little is known about microvascular changes and endothelial functie and the possible beneficial effect of physical exercise in patients with COPD.

Study objective

-To determine the presence of changes in the retinal microvasculature and endothelial function in patients with COPD (part 1)

-To determine the effect of physical exercise on microvasculare reactivity in patients with COPD and the effect of pulmonary rehabilitation on function of the retinal microvasculature and endothelial in patients with COPD (part 2).

Study design

prospective observational study.

Study burden and risks

All interventions take place at Ciro+ in Horn as part of regular pulmonary rehabilitation. In addition, retina photos will be taken in participating patients and potentially a measurement of endothelial function. When taking the retina 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.

Contacts

Public Ciro+

Hornerheide 1 Horn 6085 NM NL **Scientific** Ciro+

Hornerheide 1 Horn 6085 NM NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

- COPD as a primary diagnosis according to the Global Initiative For Chronic Obstructive Pulmonary 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+ (study part 2)

Exclusion criteria

- Lack of motivation for voluntary participation in this study.

- 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 retinopathy, which makes it impossible to analyze the microvasculature of the retina.

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	12-07-2016
Enrollment:	246
Туре:	Actual

Ethics review

Approved WMO	
Date:	27-06-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	04-04-2017

Application type: Review commission: Amendment MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26359 Source: Nationaal Trial Register Title:

In other registers

Register	ID
ССМО	NL56813.100.16
OMON	NL-OMON26359

Study results

Date completed:	30-04-2018
Actual enrolment:	250