Exercise-induced oxidative stress and peripheral muscle dysfunction in COPD; single-leg ergometer test versus whole-body exercise test.

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To investigate (1) whether basal levels of oxidative stress differs between COPD patients and healthy volunteers and (2) whether exercise-induced oxidative stress after a single-leg ergometer test differs between patients and healthy controls (3) to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Observational invasive

Summary

ID

NL-OMON30201

Source
ToetsingOnline

Brief title
Exercise-induced oxidative stress in COPD

Condition

- Muscle disorders
- Respiratory disorders NEC

Synonym
chronic lung disease, COPD

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: COPD, exercise, oxidatieve stress, peripheral muscle dysfunction

Outcome measures

Primary outcome

Various parameters of oxidative stress will be analyzed in blood, urine as well in exhaled breath. These pulmonary and systemic oxidative stress markers will be compared between COPD patients and healthy controls at rest and during exercise. Mechanical efficiency and endurance of the quadriceps femoris muscle in COPD versus healthy controls will be tested with the single-leg ergometer test.

Secondary outcome

To investigate possible determinants of quadriceps femoris muscle endurance (impairment of airway obstruction, exercise capacity, daily activity level, leg muscle strength, total body and leg FFM).

Study description

Background summary

Peripheral muscle dysfunction, which is now recognized as one of the main systemic effects of chronic obstructive pulmonary disease (COPD), contributes greatly to the exercise intolerance and reduced quality of life of COPD patients. This peripheral muscle dysfunction in COPD has primarily been explained by the sedentary lifestyle commonly observed in patients. However, evidence has been accumulating that a sedentary lifestyle is unlikely to be the sole factor involved in the myopathy of COPD patients. One hypothesis is that

exercise-induced oxidative stress can result in structural and functional muscle abnormalities in COPD.

Study objective

To investigate (1) whether basal levels of oxidative stress differs between COPD patients and healthy volunteers and (2) whether exercise-induced oxidative stress after a single-leg ergometer test differs between patients and healthy controls (3) to compare the effects of a single-leg ergometer test versus a whole-body exercise test on oxidative stress and (4) to determine whether this oxidative stress contributes to muscle dysfunction (reduced endurance time) in patients with COPD.

Study design

This proposed study is a patient-control study, where the acute effects of exercise-induced oxidative stress markers will be evaluated.

Study burden and risks

Visit 1 (only for healthy volunteers): Medical history, smoking history, physical examination, electrocardiogram, fasting blood sample, lung function test, anthropometric measurements, questionnaire on their dietary habits and physical activity level. Subjects will then undergo a maximal symptom-limited incremental exercise test on a bicycle ergometer.
Visit 2: All subjects will re-attend at least 72 hours later to perform a submaximal (60%) cycle ergometer test.
Visit 1 is included in the rehabilitation program for the COPD patients, with the exception of the questionnaire on their dietary habits and physical activity level.
WEEK 2: Visit 3: Subjects will perform a maximal single-leg ergometer test. Three hours later a submaximal single-leg ergometer test (40%) will be performed to assess the approximately duration time. Based on the outcome of this exercise test we will divide the COPD patients into 2 groups. One group has to cycle for 5 minutes (fatiguers) and the other group has to cycle for 20 minutes (non-fatiguers). These two time points are based on the results of a pilot study.
Visit 4: At least 72 hours later subjects will perform a submaximal (40%) single-leg ergometer test.
Sampling of blood, urine and exhaled breath
Urine and venous blood samples (10 ml) will be sampled at baseline, and at two time points (immediately after, 2h after) after submaximal bicycle ergometer test (visit 2). For the single-leg ergometer exercise test (visit 4), urine and venous blood will be samples at baseline, after 5 or 20 minutes, immediately after and 2h after. The blood sampling will occur through an insertion of a cannulla into the vein. Exhaled breath will be sampled before, immediately

after and 2h after both exercise tests. The sampling of blood, urine and breath condensate is virtually without any risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Diagnosis of COPD according to the American Thoracic Society (ATS) guidelines
-No respiratory tract infection or exacerbation of their disease for at least 4 weeks before the study

Exclusion criteria

-Smokers
-Use of oxygen supplementation
-Other chronic diseases such as rheumatoid arthritis, chronic colitis and diabetes
-Cardiovascular diseases, renal diseases, liver diseases or mental diseases

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-12-2006
Enrollment:	54
Type:	Actual

Ethics review

Approved WMO

Date:	25-09-2006
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL13349.068.06