'Breath taking'
A study focussing on the metabolic response and the perception of dyspnea an fatigue during activities of daily life in patients with moderate to very severe chronic obstructive pulmonary disease (COPD) of chronic heart failure (CHF).

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1a. To compare metabolic response during ADL between patients with moderate to severe COPD and healthy age-matched control subjects.1b. To compare symptom Borg scores for dyspnoea and fatigue and heart rate during ADL between patients with moderate...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON32375

Source
ToetsingOnline

Brief title
Metabolic respons during ADLs in patients with COPD/CHF and in healthy

Condition

- Heart failures
- Respiratory disorders NEC

Synonym

Chronic Heart Failure (CHF), Chronic Obstructive Pulmonary Disease (COPD)

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: interne financiering CIRO Horn

Intervention

Keyword: ADL, CHF, COPD, Metabolic response

Outcome measures

Primary outcome

Differences in absolute and relative oxygen uptake and minute ventilation

during ADLs between patients and healthy control subjects.

Secondary outcome

Differences in absolute and relative heart rate and symptom perception for

dyspnea and fatigue during ADLs between patients and healthy control subjects.

Study description

Background summary

At present, it remains unknown whether and to what extent patients with moderate to severe COPD may have a higher oxygen uptake during activities of daily life (ADL) than healthy control subjects. Nevertheless, based on previous results, it is reasonable to hypothesize that patients with moderate to severe COPD have a higher oxygen uptake while performing the same ADL as healthy age-matched control subjects.

To the best of the knowledge of the steering committee, the metabolic response during ADL has never been studied in patients with chronic heart failure (CHF). Nevertheless, CHF patients do self-report serious difficulties with performing ADL. This however has never been linked to the systemic consequences of the disease and has never been objectified.

Study objective

1a. To compare metabolic response during ADL between patients with moderate to severe COPD and healthy age-matched control subjects.

1b. To compare symptom Borg scores for dyspnoea and fatigue and heart rate during ADL between patients with moderate to severe COPD and healthy age-matched control subjects.

2a. To compare metabolic response during ADL between patients with moderate to severe COPD and healthy age-matched control subjects.

2b. To compare symptom Borg scores for dyspnoea and fatigue and heart rate during ADL between patients with moderate to severe COPD and healthy age-matched control subjects.

Study design

All designs are cross-sectional comparative.

Study burden and risks

The current research group believes that the nature and possible extent of the burden and risks possibly related to the present protocol are nihil and acceptable.

The mobile oxycon has bene used in previous studies in health and in patients with moderate to very severe COPD during exercise tests [bijvoorbeeld: Probst et al Chest 2004] and during rehabilitation sessions [Probst et al ERJ 2006] without any adverse events.

The cardiopulmonary exercise test may be perceived as burdensome by the patients and the healthy subjects. Nevetheless, this test is necesaary to provide a refenrence value for the values obtained during ADLs. Moreover, the test will be done in a specilized surrounding and will be guided by the laboratory worker and a physician. Finally, the cardiopulmonary exercise test is part of the clinical assessment of patients before the start of a rehabilitation program [Spruit et al Lancet 2008].

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

Chronic obstructive pulmonary disease (GOLD I to IV)
Chronic heart failure (NYHA I to IV)

Exclusion criteria

Neurological diseases, endocrine diseases, locomotor diseases, long-term oxygen therapy (LTOT)

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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-07-2008
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	11-07-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-06-2009
Application type:	Amendment
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	NL22292.068.08