Impairments and complaints during activities of daily living in patients with mild COPD.

Published: 15-11-2011
Last updated: 28-04-2024

Primary Objective: Which physiological impairments and complaints are present during activities of daily living in patients with mild COPD? Secondary Objective(s): Are physiological impairments and complaints during activities of daily living...

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

Summary

ID

NL-OMON35698

Source
ToetsingOnline

Brief title
Impairments during ADL in mild COPD

Condition

- Respiratory disorders NEC

Synonym
chronic airflow limitation, chronic obstructive pulmonary disease (COPD)

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Astra Zeneca,Universitair Medisch Centrum Sint Radboud

Intervention

Keyword: activities of daily living (ADL), chronic obstructive pulmonary disease (COPD), dynamic hyperinflation (DH)

Outcome measures

Primary outcome

For the first objective, the main study parameter is dynamic hyperinflation

during ADL in patients with mild COPD and in controls. For the second

objective, the main study parameter is the difference in dynamic hyperinflation

during ADL in patients and controls after a two-year interval.

Secondary outcome

During ADL:

Ventilatory parameters: ventilation (Ve), breathing reserve (BR), Ve/maximal

ventilatory capacity (MVC), ventilatory equivalent for CO2 (Ve/VCO2), partial

pressure of end-tidal CO2 (PetCO2), breathing frequency (BF).

Operational lung volumes: inspiratory reserve volume (IRV), tidal volume (Vt)

Cardiovascular parameters: heart rate (HR), HR reserve, O2-pulse, blood

pressure

Other: oxygen consumption (VO2), dyspnea, ADL-time, gas exchange

Study description

Background summary

Most studies and also interventions focus on the more severe stages of chronic obstructive pulmonary disease (COPD). However, it has been shown that mild COPD is already related with significant health-related problems, including increased mortality, enhanced FEV1 decline, decreased muscle strength and health-related quality of life. Compared to controls, patients with mild COPD

showed exercise intolerance and experienced more dyspnea during exercise. The occurrence of air trapping (dynamic hyperinflation, DH) was suggested to cause the exercise limitation. Because of the significant health-related problems in mild COPD we hypothesize that these patients also experience difficulties during activities of daily living (ADL). Patients with mild COPD showed DH during maximal incremental exercise and therefore we hypothesize that DH will also occur during ADL in those mild COPD patients. In addition, studies investigating the behavior of physiological impairments and complaints during ADL over time have not been performed. We expect DH will be increased in COPD patients after 2 years, compared with no changes for controls.

Study objective

Primary Objective: Which physiological impairments and complaints are present during activities of daily living in patients with mild COPD?
Secondary Objective(s): Are physiological impairments and complaints during activities of daily living deteriorated after two years of follow-up in patients with mild COPD?

Study design

This observational study is set as a cross-sectional study (survey) for the primary objective. The second part of the study (secondary objective) is a prospective follow-up.

Study burden and risks

The procedures we will use for measurements of lung function and exercise capacity are part of the usual diagnostic procedure of COPD patients. The measurements of impairments during ADL carry no risks.
During this study a lot of tests will be performed in both patients with COPD and controls. For both groups this will be a chance to obtain objective insights in their health condition, which can be seen as a benefit for them. In addition general practitioners of the patients will receive a report about individual patient test results, so he can offer feedback and a possible treatment advice to improve health condition of the patient.

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

Patients: Clinically stable COPD patients with GOLD stage I (= mild COPD, a FEV1/VC ratio (forced expiratory volume in one second divided by the vital capacity) < 0.7 and FEV1 >= 80% of predicted) and >=18 years old.
Controls: Subjects with normal lung function and with similar ages and gender distribution as the patients with COPD.

Exclusion criteria

Patients: patients with long term oxygen therapy at home, with co-existing lung disease other than COPD (including asthma), with restrictive lung function, with other exercise-limiting disorders than COPD like cardiac or neuromuscular disease, or patients using β-blockers are excluded from the study.
Controls: subjects with abnormal lung function or history of lung disease, with exercise-limiting disorders like cardiac or neuromuscular disease, or using β-blockers are excluded from the study.

Study design

Design

Study type:	Observational 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):	30-11-2011
Enrollment:	125
Type:	Actual

Ethics review

Approved WMO

Date:	15-11-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL37406.091.11