Physiological and systemic effects of activities of daily living in COPD patients.

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1. Respiratory physiologyDoes severity of ventilatory impairment during ADL increase in patients with respectively COPD GOLD stages II, III and IV?2. Systemic inflammationDo ADL in COPD patients lead to an increase in systemic inflammatory markers?

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

Summary

ID

NL-OMON32002

Source
ToetsingOnline

Brief title
ADL in COPD

Condition

- Respiratory disorders NEC

Synonym
Chronic bronchitis, emphysema

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Activities of daily living, Chronic obstructive pulmonary disease, Respiratory physiology, Systemic inflammation

Outcome measures

Primary outcome

1. Respiratory physiology

Increase in severity of ventilatory impairment during ADL in patients with

respectively COPD GOLD stages II, III and IV.

2. Systemic inflammation

Increase in systemic inflammatory markers after ADL in COPD patients.

Secondary outcome

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Study description

Background summary

Chronic obstructive pulmonary disease (COPD) is a major and growing cause of morbidity and mortality throughout the world9. Major complaints of patients with COPD are dyspnea, fatigue and activity limitation. Patients commonly adapt their level of activity when they become progressively dyspnoeic, leading to further decrease of their condition. Activities of daily living (ADL), however, are necessary for daily life and losing the capability to perform them will have important repercussions on quality of life.

Respiratory physiology
Since dyspnea is the main complaint in COPD, the first part of this protocol focuses on this impairment. In healthy, during relaxed tidal breathing the lungs return to a basal level of inflation, the functional residual capacity or end-expiratory lung volume (EELV). Inspiratory capacity (IC) represents the volume available for inspiration after EELV is subtracted from total lung capacity. In COPD, however, lung hyperinflation comes up. Hyperinflation is

commonly defined as an elevation of the EELV. Dynamic hyperinflation occurs when inspiration starts before expiration has been fulfilled, which occurs in COPD patients during exercise. Inspiratory reserve volume is calculated as the difference between IC and tidal volume. When this reserve is less then 500ml a so-called dyspnea limit is reached. Several real life ADL at home were investigated in COPD patients by our group. It was shown that even ADL are leading to dynamic hyperinflation, dyspnea limit and decreased ventilatory reserve. It is not known, however, whether increase in disease severity is related with increase in ventilatory impairments during ADL.

Systemic inflammation
The second part of this protocol pays attention to systemic inflammation. Since some years COPD is not longer seen as a pulmonary disease only, but classified as a systemic disease. Stable COPD is associated with low-grade systemic inflammation. Apart from systemic inflammation, other systemic or extrapulmonary effects, like weight loss, skeletal muscle dysfunction, cardiovascular disease, depression and osteoporosis, of COPD are identified. Systemic inflammation has been suggested to play a role in the pathogenesis of extrapulmonary effects of COPD. Earlier research by our group revealed enhanced systemic inflammatory responses to both maximal and submaximal exercise and even a 6 minute walking test, a measure for functional capability, in COPD patients. It is unknown whether real ADL also produces such systemic responses. Therefore, we want to investigate the effect of these activities on systemic inflammation in COPD.

Study objective

1. Respiratory physiology
Does severity of ventilatory impairment during ADL increase in patients with respectively COPD GOLD stages II, III and IV?

2. Systemic inflammation
Do ADL in COPD patients lead to an increase in systemic inflammatory markers?

Study design

This research protocol consists of two parts. In the first part, respiratory physiology during ADL will be measured at home and in the laboratory. These measurements also serve as validation for performing ADL in a laboratory setting instead of at home, which is needed for the second part of the protocol. This second part will measure systemic inflammation during ADL in the lab. Thirty stable COPD patients will be included, 15 for validation and respiratory physiology and 15 for repiratory physiology and systemic inflammation. Patients are interviewed to identify a daily activity that cause them the most dyspnea. They are asked to perform this activity at their usual pace until symptoms limit further performance. Physiologic responses during ADL

will be measured using a portable breath-by-breath system. In our lab, a cannula will be inserted into an antecubital vein under local anesthesia to obtain blood in rest, at the end of the activity and 30 and 60 minutes afterwards to investigate markers of systemic inflammation.

Study burden and risks

The procedures used are part of the usual diagnostic procedure of COPD patients and relatively innocent.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
Nederland
Scientific
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

COPD GOLD II, III, IV patients

Exclusion criteria

Long term oxygen therapy, respiratory insufficiency (PaO2 lower than 8.0kPa, PaCO2 higher than 6.3kPa), asthma, exercise limiting disorders, exacerbation in last 6 weeks. Supplementary exclusion criteria for the systemic inflammation part: smoking, oral corticosteroids, chronic inflammatory disorders

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2008
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

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	NL22864.091.08