Correlates of the COPD Assessment Test (CAT) after stratification for GOLD stages and its response to pulmonary rehabilitation in patients with moderate to very severe COPD.

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

Summary

ID

NL-OMON39909

Source
ToetsingOnline

Brief title
Correlates of CAT

Condition

- Bronchial disorders (excl neoplasms)

Synonym
COPD, emphysema or chronic bronchitis

Research involving
Human

Sponsors and support

Primary sponsor: CIRO+, expertisecentrum voor chronisch orgaanfalen
Source(s) of monetary or material Support: Astma Fonds,Astmafonds & GSK,GlaxoSmithKline

Intervention

Keyword: cardiovascular disease, CAT, COPD, Quality of life

Outcome measures

Primary outcome

The main study parameters are the CAT scores of the COPD patients and the healthy controls. With the CAT scores we can examine the absolute and percent difference between COPD patients based on severity of their COPD. Also the absolute and percent difference between COPD patients and healthy controls shall be examined. For the tertiary care patients is the change in CAT score before and after rehabilitation important. CAT scores shall also be correlated with existing HRQL questionnaires, co-morbidity, and other potential confounders.

Secondary outcome

not applicable.

Study description

Background summary

The prevalence of patients with Chronic Obstructive Pulmonary Disease (COPD) is expected to increase. The Healthy Related Quality of Life (HRQL) of COPD patients is impaired, but the assessment of HRQL is time consuming and have complex scoring algorithms for daily practice. The COPD assessment test (CAT) is a simple eight-item patient-completed questionnaire and could be used in clinical practice. Limited information is available about the correlates of

clinical physiological and psychological characteristics of COPD patients with CAT. The hypotheses of this study are:
a. (previously undiagnosed) cardiovascular disease and other co-morbidities are additional independent predictors of impaired health status, assessed with CAT, in patients with COPD
b. CAT is responsive to a comprehensive pulmonary rehabilitation programme in patients with COPD.
c. COPD patients have worse scores on the CAT than healthy elderly subjects
d. CAT is a valid instrument to assess health status in patients with mild to very severe COPD.

Study objective

The main objective of this study is the clinical, physiological and psychosocial determinants of CAT in a broad sample of patients with moderate to very severe COPD and the impact of co-morbidities on the HRQL assessed with CAT. Secondary objectives are to assess the effects of pulmonary rehabilitation on CAT scores in COPD patients, to formulate reference values for CAT using healthy controls and validate CAT in a broad sample of COPD patients.

Study design

This study is a cross sectional observational study with a longitudinal part for tertiary care patients.

Study burden and risks

All participants have one baseline visit to collect the data of the study. Besides the CAT medical history and physical examination, 4 other questionnaires, lung function, body composition, daily physical functioning test and saturation shall be assessed. Only the patients of the tertiary care have two visits, one before and one after pulmonary rehabilitation. Also the number of tests for tertiary care patients is higher but these test are part of the regular pulmonary rehabilitation assessment. The tests can cause fatigue for the participants but are used in daily clinical practice. Therefore no additional risks were expected for the participants.

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

1. Age 40-85 years
2. A diagnosis of COPD according to GOLD guidelines only applicable for COPD patients
3. Referral for assessment and pulmonary rehabilitation in Ciro+ by a chest physician only applicable for tertiary care patients.
4. Healthy, as judged by the investigator and determined by medical history and physical examination and post-bronchodilator FEV1/FVC * 70 only applicable for healthy controls

Exclusion criteria

1. For healthy controls, primary, secondary and tertiary care patients: a history of asthma, kung cancer, sarcoidosis, tuberculosis, lung fibrosis, or any other significant respiratory disease; having undergone lung surgery (e.g. lung volume reduction, lung transplantation); any clinically relevant disease which in the opinion of the investigator may influence the results of the study
2. For primary, secondary and tertiary care patients only: moderate or severe exacerbation or pneumonia requiring systemic corticosteroids, antibiotics or hospitalisation during the last 4 weeks
3. For health controls only: COPD, chronic heart failure
4. Treatment by respiratory physician or tertiary care in primary care COPD patients

5. Treatment in tertiary care setting for secondary care COPD patients
6. Participation in an interventional clinical study during the past three months (for primary and secondary care patients).

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:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-04-2012
Enrollment:	850
Type:	Actual

Ethics review

Approved WMO

Date:	23-04-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	03-09-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	22-12-2014
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

ID: 21987
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	Nederlands Trial Register: NTR3416
CCMO	NL38550.068.11
OMON	NL-OMON21987

Study results

Date completed:	07-05-2015
Actual enrolment:	873