Neuropsychological functioning of COPD patients and the influence on health status, daily functioning and the outcome of pulmonary rehabilitation.

Published: 16-10-2013
Last updated: 15-05-2024

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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-OMON40538

Source
ToetsingOnline

Brief title
Neuropsychological functioning of COPD patients.

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Chronic Obstructive Pulmonary Disease

Research involving
Human

Sponsors and support

Primary sponsor: CIRO+ B.V.

Source(s) of monetary or material Support: CIRO+

Intervention

Keyword: COPD, daily functioning, neuropsychological functioning, pulmonary rehabilitation

Outcome measures

Primary outcome

4 compound scores for the cognitive domains: motor speed, memory, cognitive flexibility and planning. Furthermore: general cognitive functioning (cognitive index; MMSE)), IQ (GIT) and subjective cognitive functioning (CFQ).

Secondary outcome

* Demographics: age, level of education and social status.

* Clinical characteristics:

- General psychological functioning: Symptom Checklist-90, Hospital Anxiety and Depression scale, Beck Depression Inventory, Utrecht coping list, Dutch personality questionnaire en St George's Respiratory Questionnaire.
- Other clinical characteristics: blood gasses, comorbidities (Charlson comorbidity index), pulmonary function, diffusion capacity, saturation measure, Obstructief Slaap Apneu Syndroom, medication, oxygen therapy, smoking behaviour, Body Mass Index, knowlegde about the lung disease, educational needs and exercise capacity (6-minute walking distance test).

* Problematic activities of daily life (*Canadian Occupational Performance Measure*).

* Patient information needs (Lung Information Needs Questionnaire).

* Brain abnormalities, including brain atrophy, white matter lesions,

hippocampal volume, vascular abnormalities, structural connectivity and

functional connectivity

Study description

Background summary

Patients with Chronic Obstructive Pulmonary Disease (COPD) may experience dyspnoea, fatigue and problems in daily functioning, despite optimal pharmacological treatment. It is important that patients follow a number of precepts in order to minimize the consequences of the illness. Before a patient is willing to follow the precepts, a patient needs to experience that the new behaviour yields more advantages, compared to the old behaviour. Patients need specific cognitive abilities in order to make a considered choice. Previous research suggests that the cognitive functions of COPD patients may be impaired. However, results of previous research are disputable. To date, remains unclear which clinical characteristics are related to cognitive functioning in COPD patients and whether and to what extent cognitive functioning is related to daily functioning, health status and the outcome of pulmonary rehabilitation.

Study objective

The first aim of this study is to determine the prevalence of cognitive impairment in COPD patients compared with persons without COPD. The second aim is to study the clinical characteristics of COPD patients with cognitive impairment. The third aim is to assess whether and to what extent cognitive functioning is related to daily functioning in COPD patients entering pulmonary rehabilitation. The fourth aim is to assess whether and to what extent cognitive functioning may influence important outcome parameters of pulmonary rehabilitation: general psychological functioning, knowledge about COPD, daily functioning and exercise capacity. The fifth aim is to study brain abnormalities in patients with COPD and the relationship with cognitive functioning and daily functioning.

Study design

The study concerns a longitudinal observational study of COPD patients during pulmonary rehabilitation. For each patient recruited in the longitudinal study a matched control will be searched for. Cognitive functioning at baseline in this subgroup will be compared with cognitive functioning in the matched controls. In 70 patients of the longitudinal study, a brain MRI will be performed.

Study burden and risks

This study will provide more insight in cognitive functioning of patients with COPD. This insight will help us to improve management programmes for COPD patients. Risks for participants are minimal. Patients have no individual benefit from participation.

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:
* Diagnosis: COPD according to the Global Initiative For Chronic Obstructive Lung Disease (GOLD) definition;Matched control group:
* Smoking status comparable with smoking status from included patient (current smoker; non smoker; former smoker)

Exclusion criteria

Patients:
* Patient is not clinically stable during 4 weeks preceding enrolment
* Previous diagnosis of dementia
* Patient does not speak Dutch well enough to participate ;Brain MRI patient group:
* The patient has a pacemaker or a cochlear implant
* The patient has a neurostimulator or other electronic implants
* The patient ever had surgery with metal implants (e.g. a magnetic implant within the jaw)
* The patient ever had a metal splinter in the eye
* The patient suffers from claustrophobia ;Matched control group:
* Diagnoses of COPD or Asthma
* Previous diagnosis of dementia
* Participant does not speak Dutch well enough to participate
* Age of the matched control differ more than 10 years from the age of the patient for who he/she was matched
* Level of education of the matched control differs more than 1 level from the level of education for who he/she was matched (according to the scoring system of the CBS).

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):	07-11-2013
Enrollment:	273
Type:	Actual

Ethics review

Approved WMO

Date:	16-10-2013
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

ID: 23902
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL45127.068.13
OMON	NL-OMON23902