Morning symptoms in-depth observational study

Published: 22-04-2015
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To investigate the occurrence and burden of morning symptoms in outpatients diagnosed with COPD gold II-IV.

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

Summary

ID

NL-OMON41909

Source
ToetsingOnline

Brief title
MODAS

Condition

- Respiratory disorders NEC

Synonym
COPD: Chronic Obstructive Pulmonary Disease

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Novartis

Intervention

Keyword: COPD, Dyspnea, Morningsymptoms, MoveMonitor

Outcome measures

Primary outcome

The primary endpoint is:

The occurrence and burden of morning symptoms. This will be assessed by

applying the Morning Symptoms questionnaire.

Secondary outcome

• Spirometry measures (VC, FVC, IC, FEV1)

• Lung volumes (FRC, RV and TLC)

• Physical function test (6 minute walking test)

• MRC Dyspnea scale

• St. George Respiratory Questionnaire (SGRQ)

• Clinical COPD questionnaire (CCQ)

• International physical activity questionnaire (IPAQ)

• COPD assesment test (CAT)

• COPD and Asthma Sleep Impact Scale (CASIS)

• Hospital Anxiety and Depression Scale (HADS)

• PROactive Physical Activity in COPD (C-PPAC)

• Absolute number of eosinophils

• Expression of different pro- and anti-inflammatory genes

• Monitoring of the following parameters by using the MoveMonitor (mcRoberts):

o intensity of walking

o mean duration of sitting periods

o mean duration of standing

o nocturnal unrest and

o pattern analysis of sleeping quality.

Study description

Background summary

Recent findings suggest that symptoms of patients with COPD vary throughout the day. Especially in the morning, patients seem to present with an increased symptom load. However, it is not clear whether this is an common characteristic of symptomatic patients with COPD, or rather represents a specific phenotype of COPD patients.

Study objective

To investigate the occurrence and burden of morning symptoms in outpatients diagnosed with COPD gold II-IV.

Study design

Single center, cross sectional study design.

Study burden and risks

This study includes one visit at the Leiden University Medical Center. At this visit participants will be subjected to a physical examination, vital signs will be tested and information regarding medical history and demography, including ethnicity, will be obtained. Subsequently, pulmonary function tests will be performed, blood will be drawn, questionnaires will be filled out and a physical performance test will be conducted. Finally, a MoveMonitor (mcRoberts) will be provided to the participants, which will measure daily and nightly activity over a period of one week. After wearing the device for seven successive days, participants will return the MoveMonitor (mcRoberts) by mail using provided material by the site. In addition, they will fill out 1 questionnaire and send this back to the site accompanied by the MoveMonitor. Considering the observational nature of this study, the risks are deemed negligible.

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

COPD stage II-IV diagnosed according to GOLD
Aged between >= 40 years and <= 80 years
Minimum of 10 pack years of smoking

Exclusion criteria

Diagnosis of asthma
Exacerbation of COPD within the past 2 months. See protocol page 9 for details.
History of sensitization to allergens
Significant other lung disease
Comorbidities and severe pain syndromes, which impair exercise capacity
Interfering malignant diseases
Clinical signs of acute heart failure
Serious mental impairment. See protocol page 9 for details

Current participation in a clinical rehabilitation programme

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-09-2015
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	22-04-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	14-08-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL51951.058.15

Study results

Date completed:	28-02-2017
Actual enrolment:	80