Non-interventional cross-over study to reduce items of the draft PROactive tools as a measure of physical activity in daily life in patients with 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-OMON37932

Source
ToetsingOnline

Brief title
PROactive

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Chronic Obstructive Pulmonary Disease, COPD

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: EU;Innovative Medicines Initiative (IMI)

Intervention

Keyword: COPD, physical activity, Questionnaire

Outcome measures

Primary outcome

The primary outcome parameter is the inital validation and itemreduction of the

draft questionnaire.

Secondary outcome

not applicable

Study description

Background summary

In the next decade Chronic Obstructive Pulmonary Disease (COPD) will affect an increasing number of European
citizens. Physical inactivity and symptoms during physical activity are a hallmark of COPD and inactivity itself
contributes to the diseaes progression. The inability to participate in daily activities is an important consequence of
COPD experiened by patients on a daily basis. Improvement of the ability to participate in physicial activity with minimal
symptoms is an important patient centred target in the management of COPD. Despite its importance, currently no
Patient Reported Outcome (PRO) captures physical activity in daily life in a way that is maximally reflects the
experience of COPD patients.

Study objective

The purpose of the study is initial validation and item reduction of the draft questionnaire. This information will be used to improve and further develop the questionnaire into an instrument that will adequately measure physical activity in patients with COPD.

Study design

The study is made up of three sections:

Period 1, total duration 6 weeks:
All patients start with a number of physical examinations and are asked to complete questionnaires. They are then randomized to 2 groups. Half of the participants (Group A) begin with the first two week test period in which they are asked to complete the daily questionnaire and are asked to wear a pedometer. This is followed by a rest period of 2 weeks and ends with the 2-week test period in which they only have to wear the pedometer. The other half (group B) begins with wearing the pedometer for two weeks followed by a rest period of 2 weeks and ends with the two week test period during which they are asked to complete the daily questionnaire and have to wear the pedometer. The two-week periods always begin and end with a visit to the clinic. During the first visit they undergo physical examinations and complete questionnaires, on the second, third and fourth visit they are asked to fill in questionnaires and either receive or return the pedometer.
A small proportion of patients (11) is recruited during an exacerbation (defined as a hospitalization as a result of worsening of pulmonary symptoms). These patients start the study after approval has been given by the attending pulmonologist. The study procedure is identical to that of the stable group with one exception. They undergo additional physical examinations during visit 4.

Period 2, follow-up after 6 months:
All patients undergo physical examinations and asked to complete questionnaires during the first visit of this round (visit number 5) including the clinical visit questionnaire. Consecutively they all have a 1 week period during which they wear three pedometers (small devices attached to a single elastic belt). The follow-up round ends with a second visit to the clinic (visit number 6) in which they are asked to complete questionnaires and return the pedometer.

Period 3, follow-up 12 months after the start of the study:
All patients undergo physical examinations and asked to complete questionnaires during the first visit (visit number 7) including the clinical visit questionnaire. Consecutively they all have a 1 week period during which they wear three pedometers (small devices attached to a single elastic belt). The follow-up round ends with a second visit to the clinic (visit number 8) in which they are asked to complete questionnaires and return the pedometer.

Study burden and risks

Central aim of this study is the development of a questionnaire with which the patient's experience of their physical activity and their limitations in this can be measured. In order to properly reflect the patients perspective in such a questionnaire it is of vital importance to include a heterogeneous group of COPD patients in the design and validation process.
Participation will only take patients' time. They will attend eight visits to

the hospital (four during the first 6-week period and 2 during the follow-up period), participate in one two week period during which they fill in a short questionnaire every day and they will partake in 3 two week periods during which they are asked wear a pedometer.

There is no intervention, therefore no direct benefit for the patient is expected from participation in this study. Participation in this study poses no risks, none of the physical examinations are invasive, they are mostly part of the standard COPD treatment programme .

The results of this study will contribute to future improvement of the treatment of COPD patients.

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. Provision of signed, written, and informed consent prior to conducting any study specific procedures
2. Men or women, >=40 years of age
3. Diagnosis of COPD (GOLD criteria: post bronchodilator FEV1/FVC<70%) confirmed with spirometry in stable clinical conditions. For patients recruited during an exacerbation, the diagnosis of COPD should be confirmed in stable conditions.
4. Current or ex-smokers with a smoking history equivalent to at least 10 pack years (1 pack year = 20 cigarettes smoked per day for 1 year)
5. Able to read and write and to use electronic devices and physical activity monitor

Exclusion criteria

1. Orthopaedic, neurological or other complaints that significantly impair normal biomechanical movement patterns, as judged by the investigator
2. Respiratory diseases other than COPD (e.g. asthma)
3. COPD exacerbation within 4 weeks prior to Visit 1 (only applicable for patients in the stable group)
4. Cognitive impairment, as judged by the investigator
5. Involvement in the planning and/or conduct of the study
6. Previous randomisation in the present study

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-10-2011
Enrollment:	56
Type:	Actual

Ethics review

Approved WMO Date:	04-10-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-12-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL36466.042.11