Healt status guided COPD (March)

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We hypothesize that a treatment algorithm that is based on a simple validated measure of health status (CCQ) improves quality of life (as measured on a separate scale) and other classical COPD outcome measurement parameters such as exacerbation...

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

Summary

ID

NL-OMON32772

Source
ToetsingOnline

Brief title
Health status guided COPD Care (MARCH)

Condition

- Respiratory disorders NEC

Synonym
chronic bronchitis, COPD

Research involving
Human

Sponsors and support

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

Intervention

Keyword: CCQ, COPD, General practice, Health Status

Outcome measures

Primary outcome

1. Change in health status (SGRQ total score) over time.

2. The second primary outcome will be the exacerbation frequency, measured by medication use. (

Secondary outcome

Change in CCQ score.

Changes in 6 minute walking distance test results.

Changes in mMRC-score and HADS-score

Hospital admissions.

Death.

Changes in lung function

Quality adjusted life years (QALY*s)

The CCQ has a total score and 3 subdomain scores. Total scores and subdomain scores will be compared to other questionnaires that address the same factors. This way it can be assessed if the subdomain scores can be used as a valid method to diagnose problems in the different domains.

• Total score: Total SGRQ

• Symptom domain: SGRQ symptom domain

• Functional domain: SGRQ section 6 and 7

• Mental domain: Depression and anxiety scale (HADS)

Study description

Background summary

Chronic Obstructive Pulmonary Disease (COPD) is a disease state characterized by airflow limitation that is not fully reversible. The airflow limitation is usually progressive and associated with an abnormal inflammatory response of the lungs to noxious particles or gases. COPD has a considerable impact on health status. Impaired exercise tolerance, fatigue, muscle weakness, depression and sleeping disorders are all features that characterize the disease.
The treatment strategies suggested by current guidelines are based primarily on a categorization on lung function impairment, more specifically the FEV1, while it is well known that the FEV1 has a poor correlation with many features of COPD, and therefore the impact the disease has on the patient. Neither symptoms nor impact of disease on the patients wellbeing have, however, been incorporated in treatment algorithms so far

Study objective

We hypothesize that a treatment algorithm that is based on a simple validated measure of health status (CCQ) improves quality of life (as measured on a separate scale) and other classical COPD outcome measurement parameters such as exacerbation frequency, patient satisfaction, and health care utilization compared to care based on current GOLD guidelines.
The research questions addressed are:
1. Does a treatment algorithm that is based on CCQ measurements alone and provides tailor-made patient guidance on both non-pharmaceutical and pharmaceutical interventions described in guidelines, improve health status as measured by SGRQ after two years of use compared to care based on guidelines?
2. Does such a treatment algorithm improve other parameters of COPD care such as exacerbation frequency, patient satisfaction, and health care utilization compared care based on current GOLD guidelines?

Study design

This is a prospective randomized controlled trial with two arms: (i) the intervention group and (ii) the FEV1-guided care group. The interventiongroup will get treatment advice bases on a treatment algorithm that is based on the CCQ-score (health status), the controlgroup will get standard treatment advice based on the FEV1 only (according to GOLD-guidelines).
This study will take place in the adherence area of LabNoord, which includes all general practices in the northern part of the Netherlands. Patients will be followed up for 2 years. There will be 4 visits per year (a total of 9 visits)

The following information will be displayed to the general practitioner for the intevention group:
• The current CCQ score and scores on each domain of the scale (symptoms, functional score and mental score).
• A graph of scores of previous visits where available.
• A warning appears if compared to the previous visit, the current CCQ has changed in excess of the minimal clinically important difference of the CCQ scale (0.4).
• The algorithm steps and treatment advice.

For the control group: The GP receives the result from the patient*s visit to LabNoord. The feedback to the GP consists out of the FEV1 values, and the advice to treat according to the current guidelines.

Intervention

Individual treatment advice which is based on a treatment algorithm based on the CCQ-score

Study burden and risks

No risk for the patient, only some extra visits

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

- diagnosis of COPD
- aged > 40 yrs
- smoking history > 10 pack-yrs
- FEV1/ forced vital capacity (FVC) <0.70 post-bronchodilator

Exclusion criteria

- Myocardial infarction less than 3 months ago
- Inability to read and understand the Dutch language.
- history of asthma or allergic rhinitis before the age of 40
- regular use of oxygen
- unstable or life-threatening comorbid condition
- Dementia

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-09-2010
Enrollment:	330
Type:	Actual

Ethics review

Approved WMO

Date:	31-08-2010
Application type:	First submission
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	NL23994.042.08