Health status guided COPD Care (MARCH).

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20748

Source
NTR

Brief title
MARCH

Health condition

COPD
Health Related Quality of Life

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: AstraZeneca

Intervention

Outcome measures

Primary outcome

Change in SGRQ over time. Because the intervention is guided by the CCQ, a different health status instrument, the SGRQ, will be used as an outcome measure. In the treatment of COPD patients in primary care, the improvement of health status and reduction of exacerbations are the main goals of treatment. In this perspective it is a logical choice to use a health

status questionnaire to guide treatment.

The second primary outcome will be the exacerbation frequency, measured by medication use. This is one of the classical COPD outcomes and exacerbations have a large impact on patients' lives.

Secondary outcome

1. Change in CCQ score;

2. Changes in 6 minute walking distance test results;

3. Changes in HADS and mMRC;

4. Hospital admissions;

5. Death;

6. Changes in lung function.

Study description

Background summary

A study to explore the value of Health Status measument guided treatment of COPD in comparison to regular (NHG guideline) treatment.

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 and secondary parameters like patient satisfaction, and health care utilization compared to care based on current GOLD guidelines.

Study design

The baseline and last visit will be performed at at the general practitioner practices or nearby at physiotherapist practices.

1. Patient demographics:

A. Age, gender, marital status;

B. Educational level;

C. Employment status;

D. Postal code;

E. Smoking status, pack years;

F. Duration of COPD.
2. Co-morbidity, using the Charlson comorbidity index
http://www.medalreg.com/qhc/medal/ch1/1_13/01-13-01-ver9.php3;

3. Previous participation in: Formal smoking cessation program, pulmonary rehabilitation, reactivation;

4. Medication use;

5. Lung function:

A. FEV1 , FEV1 % predicted;

B. FVC;

C. IC;

D. Reversibility.

6. Body Mass Index;

7. Weight;

8. Length;

9. Functional exercise capacity:

A. 6 minute walking distance test.

10. Patient reported outcomes:

A. St. George’s Respiratory Questionnaire (SGRQ);

B. CCQ;

C. Modified Medical Research Council (mMRC) dyspnoea scale;

D. EuroQol-5D;

E. Depression and anxiety Scale (HADS).

During each follow-up visit; both intervention group and FEV1-guided group. 3 times a year (excluding last visit):

1. CCQ;

2. Spirometry;

3. Pulmonary medication use;

4. Generic questionnaire about treatment offered and received;

5. Generic questionnaire about unscheduled visits to the GP or hospital because of pulmonary problems;

6. At visit 4 SGRQ, mMRC, EuroQOL-5d and HADS will be taken.

Health care professional:

1. Treatment offered to the patient will be recorded in the computer program;

2. Treating health care professional;

3. Characteristics of the patients' treating health care professional (general practitioner or practice assistant): Years in practice.

Intervention

Control treatment:

Standard COPD Treatment according the NHG guidelines.

Experimental treatment:

Standardized health status measurement by the CCQ followed by treatment advice given to the general practitioner generated by an algorithm based on the CCQ score. Depending on the general practitioner, the patient is informed by telephone or during a new consultation on the new therapy.

The GP is asked to indeed comply to the treatment advice.

After the consultation, the GP completes a questionnaire about the treatment decisions made.

The patient completes a general questionnaire about treatment(s) received since the last visit, including any hospital visits.

After the third patient visit the general practitioner receives the results of the third spirometry.

Contacts

Public
P.O.Box 30.001
C. Jong, de
Medicine Department of Primary Care University Medical Centre Groningen, Hanzeplein 1
Groningen 9700 RB
The Netherlands
Scientific
P.O.Box 30.001
C. Jong, de
Medicine Department of Primary Care University Medical Centre Groningen, Hanzeplein 1
Groningen 9700 RB
The Netherlands

Eligibility criteria

Inclusion criteria

1. Diagnosis of COPD;

2. Aged 40 yrs;

3. Smoking history: 10 pack-yrs;

4. FEV1/ forced vital capacity (FVC) <0.70 post bronchodilator.

Exclusion criteria

1. Myocardial infarction less than 3 months ago;

2. Inability to read and understand the Dutch language;

3. History of asthma or allergic rhinitis before the age of 40;

4. Regular use of oxygen;

5. Unstable or life-threatening comorbid condition (as judged by the investigator);

6. Dementia.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2008
Enrollment:	330
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-12-2010
Application type:	First submission

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
NTR-new	NL2525
NTR-old	NTR2643
Other	METC UMCG : 2008/187
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A