Health status guided COPD Care (MARCH).

Gepubliceerd: 07-12-2010 Laatst bijgewerkt: 13-12-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20748

Bron
NTR

Verkorte titel
MARCH

Aandoening

COPD
Health Related Quality of Life

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: AstraZeneca

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Diagnosis of COPD;

2. Aged 40 yrs;

3. Smoking history: 10 pack-yrs;

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2008
Aantal proefpersonen:	330
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-12-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2525
NTR-old	NTR2643
Ander register	METC UMCG : 2008/187
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A