Clinical, physiological and psychosocial determinants of the COPD Assessment Test (CAT).

Gepubliceerd: 02-05-2012 Laatst bijgewerkt: 15-05-2024

1. (Previously undiagnosed) cardiovascular disease (heart failure/vascular abnormalities/coronary artery disease), metabolic syndrome and other co-morbidities are additional independent predictors of impaired health status, assessed with CAT, in...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21987

Bron
NTR

Aandoening

Health status, COPD, heart failure as comorbidity

Ondersteuning

Primaire sponsor: CIRO+, Centre of expertise for chronic organ failure, Horn, the Netherlands
Overige ondersteuning: GlaxoSmithKline, Astmafonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

CAT scores of COPD patients and healthy controls; change in CAT score before and after rehabilitation; correlates of CAT scores (i.e., health status questionnaires, co-morbidity, other

potential confounders).

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

The CAT is a simple eight-item patientcompleted questionnaire and could be used in clinical practice.

Objectives:

Study clinical, physiological and psychosocial determinants of CAT in a broad sample of patients with moderate to very severe COPD and the impact of co-morbidities on health status assessed with CAT; assess the effects of pulmonary rehabilitation on CAT scores in COPD patients; formulate reference values for CAT using healthy controls; validate CAT in a broad sample of COPD patients.

Study design:

Cross sectional observational study with a longitudinal part for tertiary care patients.

Study population:

Broad range of COPD patients (100 COPD patients from primary care setting, 100 COPD patients from secondary care and 600 COPD patients of the tertiary care) between 40 and 85 years old and 150 healthy controls.

Primary study parameters/outcome of the study:

CAT scores of COPD patients and healthy controls; change in CAT score before and after rehabilitation; correlates of CAT scores (i.e., health status questionnaires, co-morbidity, other potential confounders).

Doel van het onderzoek

1. (Previously undiagnosed) cardiovascular disease (heart failure/vascular abnormalities/coronary artery disease), metabolic syndrome and other co-morbidities are additional independent predictors of impaired health status, assessed with CAT, in patients with COPD, irrespective of the severity of airflow limitation;

2. CAT is responsive to a comprehensive pulmonary rehabilitation programme in patients with COPD;

3. COPD patients have worse scores on the CAT than healthy elderly subjects;

4. CAT is a valid instrument to assess health status in patients with mild to very severe COPD;

5. CAT scores correlate well with other questionnaires (i.e., SGRQ-C, CCQ).

Onderzoeksopzet

All participants have one baseline visit to collect the data of the study. Only tertiary care patients have two visits, one before and one after pulmonary rehabilitation.

Onderzoeksproduct en/of interventie

There is no intervention. Tertiary care patients will receive a regular pulmonary rehabilitation program which is part of their routine treatment.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 40-85 years;

2. COPD patients: Diagnosis of COPD according to GOLD guidelines;

3. Healthy controls: Healthy, as judged by the investigator.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. History of a significant respiratory disease; having undergone lung surgery; any clinically relevant disease which in the opinion of the investigator may influence the results of the study;

2. Moderate or severe exacerbation or pneumonia requiring systemic corticosteroids, antibiotics or hospitalisation during the last 4 weeks;

3. For healthy controls only: COPD, chronic heart failure.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	25-04-2012

Aantal proefpersonen:	850
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	02-05-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39909
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3263
NTR-old	NTR3416
CCMO	NL38550.068.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39909

Resultaten

Samenvatting resultaten
N/A