Pilot study COPE III

Gepubliceerd: 16-11-2008 Laatst bijgewerkt: 18-08-2022

Patients with a combination of COPD and CHF who receive a small-group community based reactivation programme will have a higher exercise capacity and quality of life after completing the programme compared to before.

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

Samenvatting

ID

NL-OMON26380

Bron
NTR

Verkorte titel
Pilot study COPE III

Aandoening

intervention, COPD, heart failure, reactivation

interventie, COPD, hartfalen, reactivatie

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente
Overige ondersteuning: The Astma Fonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure is exercise capacity, measured with the six minute walking test.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Congestive heart failure (CHF) is an important co-morbidity in patients with chronic obstructive pulmonary disease (COPD). The beneficial effects of community based reactivation programmes on exercise tolerance have already been demonstrated in patients with solely COPD or solely CHF. However, the evidence for treatment of patients with a combination of COPD and CHF is surprisingly slim since patients with co-morbidity are more or less routinely excluded from the majority of studies.

Objective:
This pilot study will investigate whether patients with both COPD and CHF who participated in a community based reactivation programme have a higher exercise capacity and a better health related quality of life after the programme in comparison with before.

Study design:
The design of the study is a pilot intervention study with a measurement before and after the study.
Study population: Nine patients, aged between 40 and 75 years, with a combination of COPD (GOLD II-III) and CHF (NHYA II-III) will be included in this study. The patients are at least four weeks hemodynamically and respiratory stable and on a stable drug regimen with regard to both COPD and CHF. Patients will be recruited from the out-patient departments of pulmonology and cardiology of Medisch Spectrum Twente in Enschede.

Intervention:
The patients will participate in a 10 weeks community based reactivation programme under supervision of a physiotherapist. The programme contains cycling, walking, lifting and muscle strength training of the m. Quadriceps. Two self-management session under supervision of a nurse practioner will also be part of the intervention.

Main study parameters/endpoints:
The primary outcome measure is exercise capacity, measured with the six minute walking test. Secondary outcome measure is health related quality of life measured with disease specific and generic questionnaires.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The risk of the study is negligible. Patients will train under supervision of in COPD and heart failure trained physiotherapists. The physiotherapists will stop or modify the training intervention when one of the following symptoms occur:
1) marked shortness of breath or fatigue (Borg scale >13);
2) respiratory rate > 40/minute during exercise;

3) weight gain of more than two kilograms within 2-3 days.
The patients have to come three times to the hospital to undergo physical tests and to fill in questionnaires.

Doel van het onderzoek

Patients with a combination of COPD and CHF who receive a small-group community based reactivation programme will have a higher exercise capacity and quality of life after completing the programme compared to before.

Onderzoeksopzet

10 weeks training, a measurement before and after the training

Onderzoeksproduct en/of interventie

The patients will participate in a 10 weeks community based reactivation programme under supervision of a physiotherapist. The programme contains cycling, walking, lifting and muscle strength training of the m. Quadriceps. Two self-management session under supervision of a nurse practioner will also be part of the intervention.

Contactpersonen

Publiek

Medisch Spectrum Twente Hospital
Department of Pulmonology
PO Box 50.000
P.D.L.P.M. Valk, van der
Enschede 7500 KA
The Netherlands
+31 (0)53 4872610

Wetenschappelijk

Medisch Spectrum Twente Hospital
Department of Pulmonology

PO Box 50.000
P.D.L.P.M. Valk, van der
Enschede 7500 KA
The Netherlands
+31 (0)53 4872610

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age between 40 and 75

2. A clinical diagnosis of COPD defined by the GOLD-criteria stage 2 and 3

3. A diagnosis of CHF; New York Heart Association (NYHA) class II-III

4. Left ventricular ejection fraction (LVEF) < 40% by echocardiogram, within 2 months before inclusion

5. A history of smoking of a least 10 pack-years

6. Hemodynamically and respiratory stable and on a stable drug regimen with regard to both COPD and CHF for at least four weeks

7. Able to understand, read and write Dutch.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Serious other diseases with a low survival rate

2. Other diseases which generate symptoms of dyspnoea and/or decreased exercise capacity

3. Severe psychiatric illness, diagnosed by anamnesis

4. Severe anaemia (Hb<6)

5. Less than 1 year out of pulmonary of cardiac rehabilitation

6. Disorders or progressive diseases, which seriously influence the ability to walk (e.g. amputation, paralysis, claudicatio intermittens)

7. Medication use of inhibin, buflomedil, ginkgo, pentoxifylinne

8. Poorly regulated diabetes mellitus

9. Resting respiratory rate > 30 breaths/min

10. Resting heart rate > 110 beats/min in rest or atrial fibrillation with a ventricular rate > 100/min at rest

11. Sustained ventricular tachycardias not protected by ICD

12. Indication for a revascularisation intervention

13. A pulmonary embolism or a deep venous thrombosis less than a half year back

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2008
Aantal proefpersonen:	9
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-11-2008
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	NL1467
NTR-old	NTR1536
Ander register	: P08-43
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A