Pilot study COPE III

No registrations found.

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

Summary

ID

NL-OMON26380

Source
NTR

Brief title
Pilot study COPE III

Health condition

intervention, COPD, heart failure, reactivation

interventie, COPD, hartfalen, reactivatie

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: The Astma Fonds

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary outcome measure is health related quality of life and health status measured with disease specific (CCQ, CRQ, MLHFQ) and generic questionnaires (MRC).

Also exercise capacity will be measured with the Incremental Shuttle Walk Test.

Study description

Background summary

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.

Study objective

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.

Study design

10 weeks training, a measurement before and after the training

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2008
Enrollment:	9
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-11-2008
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	NL1467
NTR-old	NTR1536
Other	: P08-43
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A