ADLs before and after rehabilitation in patients with COPD and CHF

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25908

Source
Nationaal Trial Register

Health condition

Chronic Obstructive Pulmonary Disease (COPD), Chronic Heart Failure (CHF)

Sponsors and support

Primary sponsor: Ciro+
Source(s) of monetary or material Support: Ciro+

Intervention

Outcome measures

Primary outcome

The difference in ventilation and oxygen uptake during the performance of ADL before and after rehabilitation.

Secondary outcome

1.Difference in physical activity
2.Difference in heart rate
3.Difference in time to accomplish the ADLs 4.Difference in Borg symptom scores after the

performance of ADLs
5.Differences in COPM (patients scores on performance and satisfaction)

Study description

Background summary

Background of the study:
The degree and impact of dyspnea during ADLs in patients with COPD and CHF is worse compared to healthy elderly subjects. Various non-pharmacological interventions, like exercise training and energy conservation techniques, can be considered to reduce the task-related dyspnea sensation and, in turn, improve the performance of ADLs in COPD and CHF. However, its effects have never been studied. Therefore, there is a clear rationale to study the effects on the performance of domestic ADLs in patients with COPD and CHF after a program of high-intensity interval training in combination with occupational therapy.

Objective of the study:
To study the effects of pulmonary rehabilitation on daily physical activity in patients with COPD and CHF. It seems reasonable to hypothesize that an improved sub-maximal performance capacity following pulmonary rehabilitation and the correct use of ECTs will result in a lower task-related metabolic load and reduce the burden of ADLs in patients with COPD and CHF.

Study design:
Longitudinal observational design.

Study population:
Patients with clinically stable COPD and CHF entering rehabilitation at Ciro+.

Primary study parameters/outcome of the study:
The difference in ventilation and oxygen uptake during the performance of ADL before and after rehabilitation.

Secundary study parameters/outcome of the study (if applicable):
-Difference in physical activity
-Difference in heart rate
-Difference in time to accomplish the ADLs -Difference in Borg symptom scores after the performance of ADLs
-Differences in COPM (patients scores on performance and satisfaction)

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):
All intervention take place at Ciro+ in Horn as part of regular pulmonary rehabilitation. In addition, an extra test (cardiopulmonary exercise test) will be added to the post-rehabilitation assessment Furthermore, patients will perform 3 ADL-tests. The risks of participation in the

study are almost zero.

Study objective

To study the effects of pulmonary rehabilitation on daily physical activity in patients with COPD and CHF. It seems reasonable to hypothesize that an improved sub-maximal performance capacity following pulmonary rehabilitation and the correct use of ECTs will result in a lower task-related metabolic load and reduce the burden of ADLs in patients with COPD and CHF.

Study design

Patients will be asked to perform 2 ADL-tests before and 1 ADL-test after rehabilitation

Intervention

ADL-test before and after rehabilitation

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with COPD as a primary diagnosis according to the Global Initiative For Chronic Obstructive Pulmonary Lung Disease (GOLD) definition: ¡±Chronic obstructive pulmonary disease (COPD) is a preventable and treatable disease with some significant extrapulmonary effects that may contribute to the severity in individual patients. Its pulmonary component is characterized by airflow limitation that is not fully reversible.The airflow limitation is usually progressive and associated with an abnormal inflammatory response of the lung to noxious particles or gases¡±. COPD is diagnosed by a chest physician. Patients with mild (GOLDI; FEV1/FVC<70% and FEV1¡Ý80% of predicted value) to very severe (GOLDIV; FEV1/FVC<70% and FEV1<30% of predicted value) COPD will be included in the study. OR
2. Patients with CHF as a primary diagnosis according to the American College of Cardiology and American Heart Association definition: ¡°Heart failure is a complex clinical syndrome that can resultfrom any structural or functional cardiac disorder that impairs the ability of the ventricle to fill with or eject blood¡±. CHF is diagnosed by a cardiologist. Patients with mild (NYHA class I) to severe (NYHA class IV) will be included in the study.
3. Clinically stable on the basis of clinical picture by chest physician or cardiologist.
4. Treated according to the current international guidelines.
5. Permission for voluntary participation. Patients will be asked after baseline assessment and have to sign an informed consent.

Exclusion criteria

1. Neuromuscular co-morbidities. Patients with neuromuscular co-morbidities can experience problems, not caused by COPD or CHF, during the performance of the activities of daily life.
2. Lack of motivation for voluntary participation in this study.
3. Patients with long-term oxygen therapy use will be excluded for measurements of metabolic load.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2014
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-02-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45122
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4307
NTR-old	NTR4452
CCMO	NL46935.068.13
OMON	NL-OMON45122

Study results