The effect of a walking bike on exercise capacity in patients with COPD and chronic heart failure

Published: 21-12-2011
Last updated: 30-04-2024

Primary Objective: In 2 study groups, patients with COPD and patients with chronic heart failure:• To investigate whether, in comparison to unaided walking, the increase in 6 minute walking distance (6MWD) using a walking bike is greater than the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON35160

Source
ToetsingOnline

Brief title
Walking bike in COPD and chronic heart failure

Condition

- Heart failures
- Bronchial disorders (excl neoplasms)

Synonym
chronic heart failure, COPD

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Stichting Longgeneeskunde Fryslan

Intervention

Keyword: chronic heart failure, COPD, walk test, walking bike

Outcome measures

Primary outcome

The change (in meters) in 6 minute walking distance using a rollator versus a walking bike

Secondary outcome

The changes in dyspnea (Borg), leg fatigue (Borg), heart rate, breathing frequency, pulse, oxygen saturation, and inspiratory capacity (IC) during the walking tests. Differences in levels of shame (Borg score) and satisfaction (adjusted QUEST score) with rollator vs walking bike. Differences between patients with COPD and chronic heart failure with respect to responses on walking with rollator versus walking bike. Baseline characteristics will be used to identify potential predictors of response.

Study description

Background summary

COPD as well as chronic heart failure is characterized by reduced exercise capacity, which is associated with dyspnea and fatigue. Since patients with COPD and patients with chronic heart failure experience such severe impairment, wheeled walking aids might be beneficial.
In chronic heart failure the effect of walking aids has not been investigated yet, whereas in COPD the use of a rollator consistently showed some improvement in walking distance, dyspnea, and oxygen saturation, especially in the more severely impaired patients. However rollator use in daily practice seems somewhat limited, probably due to shame, so a more dynamic looking aid, such as a walking bike, may be worthwhile to investigate.
The potential increase in exercise capacity using a walking bike as compared to a rollator might be due to several reasons. The walking bike strongly reduces

weight-bearing by the lower extremities, which is supposed to improve walking efficiency in patients with COPD as well as chronic heart failure. In addition, arm-support might increase ventilatory capacity probably by improved function of the accessory muscles that expand the rib cage. This beneficial effect is assumed to be of greater importance in patients with COPD , whose diaphragms are flattened and ineffective, because such patients depend more on the inspiratory muscles of the rib cage as compared to patients with chronic heart failure. In this perspective we hypothesize that both patients with COPD and with chronic heart failure will benefit from walking with a walking bike, with the most benefit being expected for the COPD patients.

Study objective

Primary Objective:
In 2 study groups, patients with COPD and patients with chronic heart failure:
• To investigate whether, in comparison to unaided walking, the increase in 6 minute walking distance (6MWD) using a walking bike is greater than the increase in 6MWD due to walking with a rollator.

Secondary Objective(s):
In 2 study groups, patients with COPD and patients with chronic heart failure:
• To investigate whether, in comparison to unaided walking, the decrease in dyspnea after walking a fixed distance (400 m test) using a walking bike is greater than the decrease in dyspnea due to walking with a rollator.
• To investigate the effects of the use of a walking bike versus a rollator on several additional physiologic and user friendliness variables: heart rate, breathing frequency, pulse, oxygen saturation, inspiratory capacity, dyspnea, fatigue, satisfaction with equipment and levels of shame during the 6-min walk test and 400 meter test.
• To investigate whether there are differences between patients with COPD and chronic heart failure with respect to responses on walking with rollator versus walking bike
• To investigate whether predicting factors of beneficial effects of walking with rollator or walking bike can be detected

Study design

This will be a randomized crossover intervention study

Intervention

All patients will perform 6MWT*s and 400m tests using a walking bike or rollator in random order.

Study burden and risks

For this study there are no major risks involved. Most procedures are part of the standard procedures at the outpatient clinics of our hospital.
The results of this study may be important for the group of patients with COPD and chronic heart failure as it will show whether a walking bike is able to improve exercise capacity in these disabled patients and might thereby be an device that has potential to improve their quality of life. As such, we consider the balance between risks and discomfort for the patient and the possible benefit for these patient groups in the future acceptable.

Contacts

Public
Medisch Centrum Leeuwarden

H Dunantweg 2
8934AD Leeuwarden
NL
Scientific
Medisch Centrum Leeuwarden

H Dunantweg 2
8934AD Leeuwarden
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All patients:
45-80 yr, familiar with 6MWT;group 1COPD:

pulmonologist's diagnosis of COPD Gold II or III;group 2 chronic heart failure:
cardiologist's diagnosis of chronic heart failure NYHA 3 or 4

Exclusion criteria

All patients:
Disability limiting the ability to walk
Need for oxygen supplementation during exercise
Being used to walking with walking aid;group 1 COPD:
exacerbation COPD last 6 wks
history of congestive heart failure;group 2 chronic heart failure:
cardiac deterioration leading to hospital admission last 6 weeks
COPD

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2012
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	21-12-2011
Application type:	First submission

Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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
CCMO	NL38594.099.11