

'Air to walk'

A study focussing on the effects of 2 walking aids on the functional mobility in patients with moderate to very severe chronic obstructive pulmonary disease (COPD)

Published: 14-11-2008

Last updated: 06-05-2024

D1. Comparing the made distance in meters within a fixed time between a walker and a walk-bike used by COPD patients. D2. Comparing the walking time and distance on an outdoor track between a walker and a walk-bike used by COPD patients.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON36911

Source

ToetsingOnline

Brief title

Functional mobility in COPD.

Condition

- Respiratory disorders NEC

Synonym

Chronic Obstructive Pulmonary Disease (COPD)

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: COPD, Functional mobility, Metabolic response, Walking aid

Outcome measures

Primary outcome

Difference in made distance in meters within a fixed time between the walker and the walkingbike used by COPD patients.

Difference in walking time and distance on an outdoor track between the walker and the walkingbike used by COPD patients

Secondary outcome

Difference in symptom perception, number of stops, step distance, number of steps, heart rate, oxygen uptake and ventilation within a fixed time between the walker and the walk-bike used by COPD patients.

Difference in symptom perception, number of stops, step distance and number of steps made on a fixed outdoor track between the walker and the walk-bike used by COPD patients

Study description

Background summary

Patients with chronic obstructive pulmonary disease still have complaints of shortness of breath and fatigue in daily functioning despite optimal pharmaceutical treatment. Consequently they suffer from a limited mobility.

Study objective

D1. Comparing the made distance in meters within a fixed time between a walker and a walk-bike used by COPD patients.

D2. Comparing the walking time and distance on an outdoor track between a walker and a walk-bike used by COPD patients.

Study design

A prospective randomised controlled cross over trial.

Intervention

A rollator and a walk-bike.

Study burden and risks

The current research group believes that the nature and possible extent of the burden and risks possibly related to the present protocol are nihil and acceptable.

The mobile oxycon had been used in previous studies in healthy subjects and patients with moderate to very severe COPD during exercise tests (for example: Probst et al Chest 2004) and during extensive rehabilitation sessions (Probst et al ERJ 2006) without any adverse events.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Chronic Obstructive Pulmonary Disease (COPD).

A walking distance of < 500 meters in a 6-min walkingtest.

Exclusion criteria

Neurological disease

Neuromuscular disorder

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-11-2008
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	rollator and walk-bike
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Date:	14-11-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO	
Date:	08-04-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO	
Date:	19-04-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL24140.068.08
Other	www.trialregister.nl