Air to walk.

No registrations found.

Ethical reviewPositive opinionStatusPendingHealth condition type-Study typeObservational non invasive

Summary

ID

NL-OMON27084

Source Nationaal Trial Register

Brief title N/A

Health condition

Chronic Obstructive Pulmonary Disease (COPD) entering pulmonary rehabilitation at CIRO Horn.

Sponsors and support

Primary sponsor: MUMC+ **Source(s) of monetary or material Support:** Fund = initiator = sponsor.

Intervention

Outcome measures

Primary outcome

Part 1:

Difference in 6-minute walking distance.

Part 2:

Difference in total time to complete an outdoor course of about 1000m.

Secondary outcome

Part 1.

Differences in sperceived symptoms, number of stops, stride length, stride frequency, number of strides, oxygen consumption, ventilation, heart rate and oxygen saturation.

Part 2.

Differences in perceived symptoms, number of stops, stride length, stride frequency, number of strides, heart rate and oxygen saturation.

Study description

Background summary

Patients with COPD generally suffer from a limited functional mobility. An improved mobility has been found following the use of a rollator. Nevertheless, we hypothesize that a new walking aid may even be more effective to improve functional mobility by partially unloading the lower limbs by sitting on a 'bike seat'. Nevertheless, this has never been studied.

Study objective

Part 1:

Previously, the use of a rollator has been shown to improve functional mobility in patients with COPD. We hypothesize that a new walking aid will result in a larger improvement in 6-minute walking distance as compared to the rollator.

Part 2:

We hypothesize that COPD patients may also improve their functional mobility on an outdoor course of about 1000m by using the new walking aid as compared to a rollator.

Study design

Part 1+2.

Patients will be asked to walk twice on 2 consequetive days. The walking aids will be used in random order.

Intervention

Rollator versus new walking aid (a 'walk-bike').

Contacts

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Eligibility criteria

Inclusion criteria

- 1. Primary diagnosis: COPD
- 2. Unaided 6-minute walking distance <400 meter ;
- 3. Clinically stable;
- 4. Signed written informed consent;

5. Capable to communicate in Dutch language.

Exclusion criteria

- 1. Neuromuscular disease;
- 2. Lon-term oxygen therapy;
- 3. Known joint disease;
- 4. Cardiac pacemaker.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	24-11-2008
Enrollment:	48
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	18-11-2008
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	NL1473
NTR-old	NTR1542
Other	NL24140.068.08 : MEC 08-3-069
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results N/A