Gait patterns in patients with COPD during the 6-minute walk test

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON41654

Source
ToetsingOnline

Brief title
Gait patterns in COPD patients

Condition

- Bronchial disorders (excl neoplasms)

Synonym
chronic bronchitis, Chronic Obstructive Pulmonary Disease (COPD), emphysema

Research involving
Human

Sponsors and support

Primary sponsor: CIRO+, expertisecentrum voor chronisch orgaanfalen
Source(s) of monetary or material Support: CIRO+;expertisecentrum voor chronisch orgaanfalen

Intervention

Keyword: 6MWT, COPD, Gait

Outcome measures

Primary outcome

- 6MWD

- variability of Centre of Mass in medio-lateral direction

Secondary outcome

- Variability of Centre of Mass (COM) in anterior-posterior (COMAP) and vertical (COMV) direction

- Centre of Pressure (COP) in medio-lateral, anterior-posterior and vertical direction, respectively COPML, COPAP, COPV

- Average walking speed

- Step length

- Stride length

- Cadence

- Number of stops (assessed by D-flow software)

- Lower-limb muscle strength and endurance (Biodex, Biodex Medical Systems Inc., New York, US)

- Transcutaneous oxygen saturation during each 6MWT in hallway and on treadmill using a handheld pulse oximeter.

- Borg scores of all 6MWT

- Lung function using post-bronchospirometry

- Resting ECG, evaluated by the physician

- Body composition using DEXA

- Balance using the TUG-test

- 6MWD in hallway

- While performing the 6MWT in the hallway and on the treadmill, the Minimod accelerometer (McRoberts, the Hague, the Netherlands; size 8.5x5.0x1.0 cm; weight 70 g) will be attached to the trunk at the height of the sacrum using an elastic belt. Matlab software (MathWorks, Eindhoven, the Netherlands) will be used to calculate step time, step length, acceleration intensity, cadence and acceleration amplitude variability.

Study description

Background summary

Patients with COPD suffer from dyspnea, which is an important cause of deterioration of functional health. Dyspnea can cause physical inactivity and worsening of the disease. Most COPD patients have therefore a limited performance in functional activities e.g. walking. Besides, previous research has pointed out that COPD patients are less active and have a different gait pattern compared to healthy persons. This directs to balance disturbances in COPD patients.
This study will be used to characterize the differences in gait patterns between COPD patients and healthy controls. Hence results can give insight in gait patterns, performance, kinetics and kinematics during walking, which can lead to improvement of evulations of activity programs and measurements of improvements in health status of COPD patients.

The hypothesis of this study is:
1. Gait patterns in COPD patients differ from healthy subjects.

Study objective

The main objective of this study is to assess more thoroughly the differences in gait patterns between COPD patients and healthy controls. Other objectives are to assess differences in gait patterns between GOLD stages and two age groups in healthy persons. Finally, to assess difference in gait pattern before and after pulmonary rehabilitation, while differentiating the location of

rehabilitation (in CIRO+ or CIRO+ rehabilitation network) .

Study design

This study is a cross sectional and observational study.

Study burden and risks

Regular pulmonary rehabilitation, baseline and outcome assessments will not be interfered in COPD patients at CRIO+ or rehabilitation network. COPD patiënts have to perform four 6MWT on the treadmill and one practice session.

Healthy controls perform 2 6MWT on the treadmill and one practice session. Furthermore, healthy controls undergo measurements, which are comparable to those of the assessments for COPD patients: 1 6MWT in hallway, lower limb muscle strength and endurance, body composition, resting ECG, lung function and balance test. These measurements are incorporated into the regular rehabilitation program at CIRO+, therefore, healthy controls are not exposed to high risks.

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

1. Aged 40-85 years (COPD patiënts en controls age group 1) and aged 20-39 (controls age group 2).
2. Diagnosis of COPD according to GOLD guidelines (stage I-IV), only applicable for COPD patients.
3. Referral for assessment in CIRO+, and pulmonary rehabilitation in CIRO+ or CIRO+ rehabilitation network.
4. Subject is able to walk without walking aids.
5. Clinically stable evaluated by the physician.

Exclusion criteria

1. Neuromuscular co-morbidities
2. Subject is unable to walk without walking aids
3. Subject with open wounds
4. Medical history of asthma, lung cancer, sarcoidosis, tubercolosis, long fibrosis, or any other significant respiratory disease; having undergone lung surgery (e.g. lung volume reduction, lung transplantation); any clinical relevant disease which in the opinion of the investigator may influence the results of the study.
5. Other significant respiratory disease or chronic heart failure in controls.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-02-2014
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	03-02-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-03-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-07-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22446
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL46880.060.13
Other	Onderzoek wordt geregistreerd zodra goedkeuring is ontvangen (op www.trialregister.nl)
OMON	NL-OMON22446

Study results

Date completed:	17-08-2017
Actual enrolment:	252