Acceleration patterns during the 6-minute walk test

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Primary objectives:-Compare the stride-interval correlations (α) of gait in COPD patients with healthy age matched adults using accelerometers.-Investigate if this information is clinically useful to distinguish between GOLD stages 1+2 / 3 / 4....

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

Summary

ID

NL-OMON34902

Source
ToetsingOnline

Brief title
Acceleration patterns during the 6-minute walk test

Condition

- Bronchial disorders (excl neoplasms)

Synonym
chronic obstructive pulmonary disease

Research involving
Human

Sponsors and support

Primary sponsor: Department of Human Movement Science
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 6-minute walk test, accelerometer, COPD

Outcome measures

Primary outcome

Acceleration patterns during the 6-minute walk test

Secondary outcome

Length, weight, age, gender, FEV1 and FVC.

Study description

Background summary

The 6-minute walk test (6MWT) is commonly used in evaluating functional exercise capacity in various chronic diseases. However, the way patients get to a certain distance is poorly investigated. Analyzing walking patterns of patients can be useful in characterizing different pathological states and functional status. Recently Hausdorff (2007) suggested detrended fluctuation analyses (DFA) as method to evaluate mobility of patients and elderly with fall risk.[1] DFA provides insight in long-range correlations in gait by a single scaling exponent α. An α towards 1.0 indicates healthy long-range, fractal correlations. On the other hand, an α closer to 0.5, indicating randomness, can be related to age-related and pathologic alterations in the locomotor control system. Besides physiological factors α can also be influenced by environmental factors. When healthy subjects are restricted to walk with a certain step frequency, time series fluctuations become more uncorrelated and α drops towards 0.5. [1] Yet when subjects walk fast, α increases toward 1.0. Decrease in α has been associated with central neurological diseases, such as Parkinson and Huntington*s disease and gait unsteadiness in the elderly. Although α does not alter in patients with peripheral limitations, [2] it is not conclusively known if α can also reflect control processes of other physiological systems. Therefore we will have a closer look at the fractal dynamics of gait in chronic obstructive pulmonary disease (COPD) patients during the 6MWT with healthy age matched subjects as reference. COPD is a highly prevalent chronic lung disease, characterized by reduced muscle function and pulmonary dysfunction. α may offer additional information on 6MWT performance that can be used to identify COPD severity.

Study objective

Primary objectives:
-Compare the stride-interval correlations (α) of gait in COPD patients with healthy age matched adults using accelerometers.
-Investigate if this information is clinically useful to distinguish between GOLD stages 1+2 / 3 / 4.

Secondary objective:
-Explore other methods to characterize walking performance during the 6MWT in COPD patients with healthy adults as reference.

Study design

Case-control study design.

All subjects will be recruited in the morning at ciro. Participants will be informed both verbally as in written. Subjects will have at least one day time for reflection before decide if they are willing to participate. The accelerometer that will be used in this study is the Minimod, McRoberts, The Hague, The Netherlands (size: 8.5 x 5.0 x 1.0 cm, weight: 70 g). This accelerometer will be attached to the trunk using an elastic belt.

Study procedure for COPD patients:
All assessments will be integrated in the clinical routine. Patients will be asked to wear the accelerometer during the 6MWT. The 6MWT will be performed two times. Only data obtained form the best test (highest distance) will be used for further analyses. The lung function test, two 6MWT*s and questionnaires before and after the 6MWT*s used for this study are already part of the clinical routine. Outcome parameters from these tests as well as date of birth, gender, weight and height will be taken from their medical recordings.

Study procedure for healthy controls:
Healthy controls will be matched with the COPD population on age, gender, height and weight, Healthy controls will be asked to walk continuously as far as possible within six minutes (6MWT). Prior to the 6MWT and immediately after the test the examiner asks the participant for self-reported dyspnea and fatigue with a ten point Borg Scale. During the test subjects will wear the accelerometer. After the first 6MWT, the Forced Expiratory Volume in One Second (FEV1) and Forced Vital Capacity (FVC) is determined using spirometry. In addition date of birth, gender, weight and height will be assessed. After these assessments, controls will be asked to do another 6MWT while wearing the accelerometer. Also before and after the second 6MWT participants will be asked to report dyspnea and fatigue. Only data obtained form the best test (highest distance) will be used for further analyses. The total duration of the study will be 30 minutes.

Study burden and risks

Not applicable

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

COPD: Forced Expiratory Volume in One Second (FEV1) / forced vital capacity (FVC) < 70%
Healthy subjects: reported to have no medical problems, FEV1 / FVC > 70%
Age > 50 yrs.

Exclusion criteria

Able to walk without a walking aid.

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:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2010
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO

Date:	26-02-2010
Application type:	First submission
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	NL30763.068.09