Reproducibility of a 6-minute cycle ergometer test protocol in patients with COPD.

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The objective of this study is to evaluate the reproducibility (CV) of a 6-minute cycle exercise performance test in patients with COPD.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract infections
Study type	Observational non invasive

Summary

ID

NL-OMON35957

Source
ToetsingOnline

Brief title
Reproducibility of a 6-minute cycle test in patients with COPD.

Condition

- Respiratory tract infections

Synonym
Chronic bronchitis, emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiopulmonary exercise tests Exercise training, COPD, Pulmonary rehabilitation

Outcome measures

Primary outcome

The CV (coefficient of variation) of the 6- minute cycle test is the main

measure of this study.

Secondary outcome

Secondary study parameters for this study are;

- Total work performed (KJ) in the test;

-Borg score for dyspnea and Borg score for perceived exertion in the legs,

before and after completion of the 6-minute cycle test;

-Saturation score (SpO2) (%)

Study description

Background summary

Patients with Chronic Obstructive Pulmonary Disease (COPD) have a reduced exercise tolerance. Therefore, improvement of exercise capacity is considered to be a key dimension of response in lung rehabilitation interventions and exercise tolerance and has become an important outcome measure for lung rehabilitation evaluation. As exercise intolerance cannot be predicted at rest, cardiopulmonary exercise tests (CPET) are used to evaluate exercise intolerance in patients with COPD. CPET is based on the principle that system failure typically occurs while the system is under stress. These tests can provide an objective measure of exercise capacity in patients with COPD as they can; identify the mechanisms limiting exercise tolerance; establish indices of the patient*s prognosis; and monitor disease progression and/ or the response to specific interventions by evaluating the changes in exercise variables before and after rehabilitation. Submaximal exercise tests such as the constant load exercise test (CLET) protocols are used to evaluate changes in exercise variables after interventions in a everyday life work rate domain. In these CLET protocols on a cycle ergometer work rate is constant (usually 75 - 85% of

peak work rate measured at an symptom limited incremental exercise test), and patients are asked to exercise as long as they can. Time to limitation (TLIM) is measured and used to evaluate intervention effects on exercise tolerance. These CLET protocols are called open- ended test protocols. In open- ended test protocols there is no clearly defined ending point of the test as the total work performed in this test depends on the exercise capacity of the patient. In contrast, in closed-ended test protocols an ending point of the test is clearly defined as the total work performed or total time is determined in advance. In time trial tests, the exercise capacity of the patient determines the time that is needed to complete the total work. The reproducibility of closed- ended time trial performance tests is much higher than open- ended performance test protocols in healthy subjects. Reproducibility of a closed- end 6 minute cycle protocol in patients with COPD has never been evaluated. The 6-minute walk (6-MWT) test is a closed-end (time is determined in advance) self paced standardized field test to evaluate exercise tolerance in patients with COPD. Because most activities of daily living are performed at submaximal levels of exertion, the 6-MWT more likely reflects the functional exercise level for daily physical activities. However, to our knowledge, there is no such closed end cycling equivalent exercise test for evaluation of performance in patients with COPD. Given the ubiquity of cycling activities in many countries (and especially the Netherlands,) and the fact that cycling is an often-used training modality in pulmonary rehabilitation, there is a need for a validated closed-ended cycling performance test. We expect closed- ended test protocols (time trials) to be more suitable than open-ended tests to assess performance capacity in patients with COPD in a clinical setting. These tests are presumed to be less sensitive to the effect of motivation and other psychological factors on exercise performance, as the end-point of the test protocol is determined in advance. This is an important issue in COPD patients since they often experience breathing discomfort during exercise.

Study objective

The objective of this study is to evaluate the reproducibility (CV) of a 6-minute cycle exercise performance test in patients with COPD.

Study design

Patients will perform the same 6-minute cycle test protocol five times in a two-week period. Between each test there is a 48 to 72 hour period. All tests will be performed at the same the time of the day. Patients will be instructed not to eat in the two hours preceding the test, and to avoid strenuous physical work 24 hours prior to the tests. Within 30 minutes before the test, patients are told to use their regular medication. An electromagnetically braked ergometer (Lode Excalibur Sport, Lode, Groningen) is used to perform the tests. The cycle ergometer was set in a linear mode; work rates increased with increased pedalling rate. After a short warm-up period (3 min, 20%Wmax)

patients will be asked to perform a maximal amount of work in 6-minutes. There is a 6-minute countdown visualised on a monitor during the test. During these tests, patients received no information about time and pedalling rate (rpm). Total work in 6 minutes to complete is the main measure of performance. The test will be aborted when pedalling rates drop below 40 rpm or when oxygen saturation (SpO2) falls below 85%. Patients are free to stop the test at any time without consequences. A modified Borg Dyspnea Scale is used to assess perceived exertion in the legs and dyspnoea before and after completion of the 6-minute cycle test.

Intervention

Not applicable.

Study burden and risks

The risk and burden in this study is deemed minimal in comparison with the regular exercise testing and exercise training in pulmonary rehabilitation programmes. Patients with comorbidities that limit their exercise tolerance will not be included in the study. Closed-end tests as the 6 - minute walk test (6MWT) are widely used to examin exercise tolerance of patients with COPD. The 6MWT has proven to be safe and the use of these tests to evaluate aerobic capacity is widely accepted. However, there is no 6- minutes cycle equivalent. The use of such a equivalent cycle test provides no additional risks as the burden to the patient is simular to the 6MWT. In this study, patient can always contact the main investigator or independent medical doctor at any time during the course of the study should they have questions or comments regarding protocol adherence tor any other questions related to the study. Patients in this study will receive an invitation letter with a written explanation of the aims and procedures of the study and a verbal explanation; Attached to the invitation letter, an explanation about the insurance will be provided.
Patients can contact investigator Willem Gosens (PhD) and the independent medical doctor, during and after the study. The research data will be analyzed, described and kept by Mr. Willem Gosens, (PhD). Patient can end their participation at any time without explanation.

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

-patient has provided written informed consent;
-patient is diagnosed with COPD (FEV1 / FVC postbronchodilatoir < 70%);
-patient is clinically stable;
-patient has stopped smoking;
-patient had an indication for lung rehabilitation and has finished lung rehabilitation (out-patient group).

Exclusion criteria

-patient is hypoxic at rest (PaO2 < 55 mg Hg);
-patient has experienced exacerbations in the last 8 weeks before commencement of the study.
-comorbidities that influence exercise tollerance

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2012
Enrollment:	22
Type:	Anticipated

Ethics review

Approved WMO

Date:	16-11-2011
Application type:	First submission
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC 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	NL36049.068.11