Exercise training in patients with COPD

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To quantify the effectiveness of one- legged exercise training in improving functional status of patients with COPD in comparison to two- legged exercise training during a 10 week pulmonary rehabilitation programme.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract infections
Study type	Interventional

Summary

ID

NL-OMON35203

Source
ToetsingOnline

Brief title
Exercise training 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: COPD, Exercise training, one leg training, rehabilitation

Outcome measures

Primary outcome

Primary outcome variable in the study is: time trial endurance performance test (sec).

Secondary outcome

Other parameters that will be measured at rest are: FEV1 (L/sec), FVC (L), Quality of life (questionnaire), ADL (questionnaire).

Parameters that will be measured during maximal exercise are Peak VE (L/min), Peak VO2 (L/min), Peak CO2 output (L/min), SaO2 (%) HR (beats/min), dyspnea (visual analog scale), f (breaths/min), peak power (W), energy expenditure (Joules).

PAEE will be measured during 7 days of free living by combined sensing of acceleration and heart rate with Actiheart-monitors.

Study description

Background summary

Improving exercise capacity is an important part of pulmonary rehabilitation programmes in patients with chronic obstructive pulmonary disease (COPD). Most patients with COPD are so limited by shortness of breath (dyspnea), even at modest levels of ventilation, that their training is restricted to low intensity training. As a result, COPD patients find it difficult to improve exercise capacity by low intensity exercise training. One- legged exercise training might allow training at a relatively higher intensity at a lower ventilatory load. Therefore, one- legged exercise training might improve exercise capacity more significantly than two- legged exercise training in patients with COPD.

Study objective

To quantify the effectiveness of one- legged exercise training in improving functional status of patients with COPD in comparison to two- legged exercise training during a 10 week pulmonary rehabilitation programme.

Study design

Patients will be randomly allocated to the one-legged or the two-legged exercise training group after completing baseline assessments. Both the groups train three times per week for a 10 week period, with 20 minute training sessions (without the w-up and c-down period). The one legged warming- up lasts 4 minutes, 2 minutes for each leg. The intensity for the warming-up for the 1L- group is set at 20% Wmax attained on the baseline one- legged incremental cycle test. Patients of the one- legged group start the test session with the leg they used at the start of the warming-up. The goal of the training sessions is to train with maximum intensity for a period of 20 minutes. If necessary, intensity will be reduced to obtain 20 minutes of cycling in the first training session. Patients of the 1L- group switch leg after 2 minutes of cycling during the training session. The 1L- group start the training session at an intensity of 60% Wmax attained on the baseline one-legged incremental test. Intensity of training in the training session is lowered when patients are not able to obtain 20 minutes of interval training (excluding the warming up and cooling down period). Training intensity will be increased by 5W when exercise duration (20 min) is reached for two successive sessions. Patients will be encouraged by the same person every test and in the same manner. Water will be available on request. Patients are free to stop the training session at any time without consequences. After the training session there is an 4 minutes one- legged cooling- down period.
Time trial performance, ventilatory parameters, quality of life (QOL), activities of daily living (ADL), physical activity energy expenditure (PAEE), dyspnea and exercise capacity parameters will be measured.

Patients of the 2L- group cycle with two legs in the 4 minutes warming- up. The intensity for the warming- up for the 2L- group is set at 20% Wmax attained on the baseline two- legged incremental test. The goal of the training sessions is to train at maximum training intensity/workload for a period of 20 minutes (excluding the warming up and cooling down). If necessary, intensity will be reduced to obtain 20 minutes of continuous cycling. The 2L- group cycle with two legs during the training sessions. They start the training session at 60% Wmax attained on the baseline two- legged incremental test. Intensity of training in the training session is lowered when patients are not able to obtain 20 minutes of interval training. Training intensity will be increased by 5W when exercise duration (20 min) is reached for two successive sessions. Toe clips are used to keep the feet on the pedals during exercise training.
Patients will be encouraged by the same person every session and in the same manner. Water will be available on request. Patients are free to stop the training session at any time without consequences. After the training session

there is a 4 minutes two- legged cooling- down period. Time trial performance, ventilatory parameters, quality of life (QOL), activities of daily living (ADL), physical activity energy expenditure (PAEE), dyspnea and exercise capacity parameters will be measured.

Intervention

One leg training. Patients in the one- legged group switch leg after 2 minutes of cycling during the training session on an electromechanically braked cycle. Patients can rest their inactive foot on a crossbar of the ergometer.

Study burden and risks

The risk and burden of this study is deemed minimal in comparison to regular exercise training in lung rehabilitation programmes. Patients with comorbidities that limit their exercise tolerance will not be included in this study.

Exercise training is seen as an important part of pulmonary rehabilitation of patients with COPD. In this study in one group, two- legged endurance rehabilitation training is replaced by one- legged endurance rehabilitation training. Using one- legged training instead of two- legged training does not involve any risks for the patients. Moreover, they are expected to experience less dyspnea (shortness of breath).
The ventilatory parameters measured in this study are routinely measured during the assessments of new COPD patients in pulmonary rehabilitation centers. There are no risks involved in using the different questionnaires of activity in daily living (ADL).

Exercise training
Exercise training is seen as an important part of pulmonary rehabilitation of patients with COPD. Using one- legged training instead of habitual two- legged training does not involve any additional risk for the patients in the one-legged exercise training group. Moreover, they are expected to experience less dyspnea (shortness of breath). Dolmage et al 9 showed that cyclic one- legged exercise training improved aerobic capacity compared with conventional two-legged training in patients with COPD.
The ventilatory parameters (FEV1, FVC, Peak VE, Peak VO2, Peak CO2, SaO2), measured in this study are routinely measured during the assessments of new COPD patients in pulmonary rehabilitation centers so there is no additional risk in measuring these parameters. The burden of using different questionnaires of activity in daily living (ADL), dyspnea and quality of life (QOL) is deemed minimal.

Time trial tests
Time trial test protocols are frequently used to evaluate performance before

and after training in healthy subjects. Time trial test protocols appear to be more reliable than open ended test protocols since their reproducibility is higher. The use of these time trial test to evaluate performance is now globally accepted. There are no additional risks of these time trial endurance exercise performance tests in comparison with the routinely used open-ended endurance exercise performance test, and therefore the risk of use of a time trial test in patients with COPD patients is deemed minimal.

Activity and heart rate monitoring by Actiheart
Accelerometry has no recorded risks despite its widespread use. Actiheart monitors are placed on the chest with ECG electrodes and have been specifically designed to cause minimal discomfort, weighing around 8 grams. Patients undergo cardio-pulmonary stress tests before allocation to the compact programme group, and therefore it is unlikely for unexpected ECG-abberations to be detected during Actiheart monitoring.

The single discomfort that is known to occasionally arise from the wearing of Actiheart monitors is minor skin-irritation from the ECG-electrodes. If at any time during the measurements subjects should indicate any hindrance or discomfort from the Actiheart, they will be asked if they wish to take the monitor off, and it will be repeated to them that they can end their participation at any moment without any consequence. Subjects can contact either the main investigator or the independent medical doctor at any time during the course of the study should they have questions regarding protocol adherence or any other questions related to the study.

Additional information:
The patients in this study will receive an invitation letter, containing 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 drs. Willem Gosens and the independent MD before, during, and after the study.
The data will be analysed, described, and kept by W. Gosens, PhD student.
Patients can end their participation at any point 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 has an indication for lung rehabilitation

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
•patient has problems adapting to the disease, requiring a more behavioural intervention (extended programme).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2009
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	28-05-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-06-2010
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	NL26791.068.09