Sinusoidal Compared With Constant Work Rate High Intensity Exercise Training In COPD Patients With Ventilatory Limitation

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON40122

Source
ToetsingOnline

Brief title
Sinusoidal exercise training in COPD.

Condition

- Respiratory disorders NEC

Synonym
COPD

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: onderzoeksgelden binnen het UMCG

Intervention

Keyword: COPD, Critical power, High Intensity Exercise Training, Sinusoidal

Outcome measures

Primary outcome

The primary outcome measure will be comparison of improvement in endurance of a work rate initially eliciting exercise limitation after 6 minutes (calculated from the power-duration relationship before and after training).

The power-duration plots of work rate vs. 1/tlim before and after training will be analyzed. The pre-training relationship will be interpolated to determine the work rate that would be tolerated for 6 minutes. The post-training power-duration relationship will be interpolated to determine the duration of exercise (tpost) at that work rate. The difference (tpost-6) represents the exercise training-induced increase in exercise duration. Using this derived measure of increased exercise endurance has the following advantages: 1) It utilizes all 4 pairs of exercise tests, increasing reliability over use of a single pair of exercise tests and 2) as the increase in exercise endurance is a strong function of the initial exercise duration, utilizing a fixed initial duration (6 minutes) will reduce the variance in exercise duration increase among subjects.

Secondary outcome

Secondary outcome measures will include:

* Change in critical power of the power-duration curve

* Change in curvature constant of the power-duration curve

* Change in iso-time ventilatory, gas exchange and heart rate responses and in

dyspnea rating in the constant work rate tests

* Change in peak VO2 and lactate threshold in the incremental exercise test

* Change in 1RM of the leg press as a measure of leg strength

Study description

Background summary

High intensity exercise training results in significant improvement in exercise capacity in patients with COPD. However, most patients do not tolerate this training regimen for long periods due to reduced breathing reserve and incapacitating breathlessness. Sinusoidal high intensity exercise is a different approach to bi-level interval training, which is the highest possible continuous exercise (with a peak of 120% of the peak work rate in an incremental test) that does not result in ventilatory limitation. This study was presented at the American Thoracic Society meetings in 2010.
Based on this study we designed an exercise training study comparing sinusoidal and cosntant work rate exercise training. We expect that an exercise training program using sinusoidal high intensity training will result in greater physiologic benefits than constant work rate training. This may result in a significant improvement in exercise capacity, muscle strength in patients with severe COPD. Improvement in exercise capacity may also improve symptoms of dyspnea in COPD patients and subsequently ameliorate the ability to perform activities of daily living and quality of life.

Study objective

The primary outcome measure will be comparison of improvement in endurance of a work rate initially eliciting exercise limitation after 6 minutes (calculated from the power-duration relationship before and after training). We will also compare improvements in critical power and curvature constant of the power-duration relationship. Further, we will compare responses to incremental exercise to determine whether increases in lactate threshold and peak oxygen uptake are greater in the group assigned to sinusoidal work rate training. Finally, we will assess increases in quadriceps strength to determine whether the periods of high muscle tension induce adaptations that increase muscle strength

Study design

All COPD patients will be evaluated with the following lung function and exercise tests in the assessment week:

Visit 1: After informed consent, pulmonary function test and incremental exercise test will be completed to assess exercise tolerance

Visit 2 &3: Two constant work rate exercise tests in each day, with at least 2 hours separating the tests, to derive the power-duration curve.

Visit 4: A constant work rate test at the critical power. After two hours of rest, leg strength testing by means of the 1 repetition maximum of the leg press will be determined.

After the assessment week, subjects will be randomly allocated to the sinusoidal exercise training program (ST) or continuous work rate exercise training program (CT). Randomization will be stratified by oxygen use (yes or no) and FEV1 (>= or < 40% predicted).

Both training programs contain exercise sessions of 45 minutes each, 3 days a week for 4 weeks. After the 4 week training program, the exercise tests performed in the assessment week will be repeated.

Intervention

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Trainingstrategies
Half of subjects will exercise at a work rate equal to critical power. The other half will exercise at a sinusoidally varying work rate such that the mean of the sine work rate is equal to the critical power and the peak of the sine work rate is set to 120% of peak work rate. After 3 minutes of unloaded cycling, exercise begins with the sine wave at its trough to assure a smooth increase in work rate. A sinusoidal period of 60 seconds will be used. The modulating sine wave work rate forcing will be generated by a computer program and applied to the work rate controller of electromagnetically-braked cycle ergometers (Cateye) through digital to analog conversion

Study burden and risks

COPD patients in the study are screened by a medical doctor on the first visit. Medical history, physical exam, pulmonary function tests, ECG and an incremental cardiopulmonary exercise test. Patients with cardiovascular or other comorbidity that constitutes a relative contraindication to a vigorous exercise program are excluded.

Before every exercise test and training patients are asked for increase in pulmonary and cardiac symptoms. Bloodpressure, heartrate and oxygen saturation are always measured. Patients are monitored during the exercise tests, measuring blood pressure, ECG and oxygen saturation.

During the exercise training patients are also monitored, measuring oxygen saturation.

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 GOLD II-IV
A minimum of 40 Watts will be required as peak work rate.

Exclusion criteria

Patients in the active phase of pulmonary rehabilitation involving exercise training and those participating in the past 18 months will be excluded.
Cardiovascular comorbidity that constitutes a relative contraindication to a vigorous exercise program (for example recent myocardial infacrtion, ventricular arythmias)

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):	15-12-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	16-12-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-05-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL42158.042.13