Effects of inspiratory muscle training in patients with chronic obstructive pulmonary disease.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23400

Source
Nationaal Trial Register

Brief title
IMTCO

Health condition

COPD, inspiratory muscle weakness
ademhalingsspierzwakte

Sponsors and support

Primary sponsor: Radboud University Medical Centre Nijmegen
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Intervention

Outcome measures

Primary outcome

6mwd.

Secondary outcome

The effects of adding IMT to a 3-months general exercise training program will be compared with a regular 3-months general exercise training program on HRQL and participation in daily physical activity in patients with COPD and inspiratory muscle weakness.

Improvements in health-related quality of life as assessed with the disease specific chronic respiratory disease questionnaire (CRDQ) and participation in objectively assessed daily physical activity and breathing pattern during exercise will be secondary outcomes. Tidal volume (VT), inspiratory time (TI), total time of the respiratory cycle (TTOT) and respiratory frequency (fR) will be assessed as parameters reflecting breathing pattern of patients. TI/TTOT (duty cycle) represents the time fraction during which the inspiratory muscles are active. Threshold IMT is supposed to lower this fraction thereby leaving more time for expiration potentially leading to less dynamic hyperinflation. Furthermore the fR/VT ratio will be monitored to assess whether breathing during exercise becomes less rapid and less shallow after IMT.

Study description

Background summary

Rationale:

Respiratory muscle weakness is commonly observed in patients with COPD and contributes to reduced exercise capacity and dypnea. It is, however, still unclear if supplemental interventions to support exercise training programs such as inspiratory muscle training (IMTresult in clinically relevant improvements for patients. Meta-analyses of RCT¡¯s in patients with COPD revealed that IMT might have most beneficial effects on exercise capacity in patients with clearly reduced inspiratory muscle strength. However, the effectiveness of these interventions, when added to general exercise training programs, needs to be tested in randomized controlled trials (RCTs).

Objective:

In this project the effects of adding IMT to a 3-months general exercise training program will be compared with a regular 3-months general exercise training program on exercise capacity, HRQL and participation in daily physical activity in patients with COPD and inspiratory muscle weakness. The effects of IMT on breathing pattern and symptoms of dyspnea and leg fatigue during exercise will be assessed as secondary objectives.

Study design:

Randomized controlled trial, multicentre.

Study population:

All patients with spirometry-proven stable COPD that are referred for outpatient pulmonary rehabilitation will be screened for inclusion. Only patients with pronounced inspiratory muscle weakness (PI,max < 60cmH2O) will be eligible to participate in the study.

Intervention:

Patients agreeing to participate will be randomized into an intervention and a control group. Both groups will follow a general exercise training program. The intervention group will

receive an additional inspiratory muscle training program at a high intensity (≥ 30% PI,max), whereas the control group will receive an inspiratory muscle training intervention at a low training intensity (¡Ü 10% PI,max).

Main study parameters/endpoints:

Improvement in the six-minute walking distance. A clinical relevant difference in improvement of the six minute walking distance between both groups is defined as 35m.

Study objective

The addition of inspiratory muscle training to a general exercise training program improves inspiratory muscle strength, exercise capacity, health related quality of life and participation in daily physical activity in patients with COPD suffering from inspiratory muscle weakness.

Study design

At start and at end of rehabilatation (3 months).

Intervention

Additional to general pulmonary rehabilatation prpgram: Inspiratory muscle training at a high intensity (≥ 30% PI,max), whereas the control group will receive an inspiratory muscle training intervention at a low training intensity (≤ 10% PI,max).

Contacts

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Eligibility criteria

Inclusion criteria

1. COPD;

2. Inspiratory muscle weakness (Pimax < 60cm H2O).

Exclusion criteria

1. Diagnosed psychiatric or cognitive disorders;

2. Progressive neurological or neuromuscular disorders;

3. Severe orthopedic problems having a major impact on daily activities;

4. Patients on the waiting list for lung transplantation;

5. Hospitalization during the previous month;

6. Previous inclusion in rehabilitation program (<1 year).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2011
Enrollment:	166
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL2848
NTR-old	NTR2990
Other	ABR nr. : 37630
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A