Inspiratory muscle training prior to peripheral muscle training in patients adolescents with Cystic Fibrosis.

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1. Is a home-based peripheral muscle training program (5BX) more effective in (a) increasing peak work rate and (b) patients* preferred occupational performance in patients with CF who are preconditioned by IMT?2. Which variables are indicators of...

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

Summary

ID

NL-OMON38371

Source
ToetsingOnline

Brief title
IMT in patients with Cystic Fibrosis

Condition

- Muscle disorders
- Congenital respiratory tract disorders

Synonym
cystic fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Beroepsorganisatie

Intervention

Keyword: exercise capacity, inspiratory muscles, patients with cystic fibrosis, training

Outcome measures

Primary outcome

The peak work rate in watts (Wpeak) achieved during the aerobic maximal exercise test (CPET).

The main study parameter of the alternative protocol is the * time recovery of phosphocreatine (1/2 time PCr recovery) after maximal exercise.

Secondary outcome

- work of breathing in rest and during exercise
- exercise capacity (except Wpeak)
- disease specific and generic Health Related Quality of Life
- habitual daily activity
- respiratory muscle function
- peripheral muscle function
- rate of perceived exertion
- patient specific goals
- co morbidity
- spirometry
- anthropometry
- use of medication and other care
- compliance to interventions
- feasibility of interventions and measurements

- type of CF gene mutation

Study description

Background summary

Cystic fibrosis (CF) primarily affects the respiratory and digestive systems in patients with CF. Due to the continual bronchial airway obstruction a chronic hyperinflation of the thorax develops, thereby decreasing the efficiency of inspiratory muscle work and increasing work of breathing (WOB) in rest and during exercise. The increased WOB and the corresponding fatigue of the inspiratory muscles (diaphragm and supportive inspiratory muscles) are thought to induce a so called respiratory muscle induced metaboreflex causing a reflex vasoconstriction of the locomotor muscle blood vessels. It is feasible that this decreased blood supply to the locomotor muscles will limit maximal exercise capacity.
The hypothesis of this study is therefore: A home-based peripheral muscle training program (Five Basic Exercises program (5BX)) is more effective in (a) increasing peak work rate and (b) patients* preferred occupational performance when it is preconditioned by inspiratory muscle training (IMT).

Study objective

1. Is a home-based peripheral muscle training program (5BX) more effective in (a) increasing peak work rate and (b) patients* preferred occupational performance in patients with CF who are preconditioned by IMT?
2. Which variables are indicators of response to 5BX, preconditioned by IMT?

Study design

This study is a double blinded randomized clinical trial. After screening for inclusion and exclusion criteria and after given approval, patients are included and followed during a maximal 6 week baseline measurement. After the baseline period and measurements at 6 weeks, participants are randomized in an IMT Training group and an IMT Sham group. After undergoing 6 weeks IMT or sham IMT and subsequent, after 6 weeks 5BX, measurements are repeated. A 6 weeks wash-out period is entered after 5BX and measurements are repeated afterwards. Additionally, we developed an alternative version of the research protocol for the previous participants in the *Skeletal Muscle Metabolism in CF* study (METC 11-084). As these patients recently successfully performed a CPET in an MR scanner (as described in METC 11-084), these patients are asked if they would like to volunteer to perform the six weeks home based training protocol (5BX) and afterwards perform the same two exercise tests, one in the MR scanner, as they previously did in study 11-084. The IMT intervention and wash-out period

will not be part of this alternative protocol.

Intervention

Included participants subsequently undergo:
- 6 weeks of standardised (sham) IMT with an inspiratory threshold-loading device (Threshold IMT, PT Medical, Leek, The Netherlands). Progression of intensity in the training group is based on rate of perceived exertion. Trainingfrequency is 5 times a week, 11 minutes a day. Patients in the Training Group start at a resistance of 30 % maximal inspiratory pressure, Sham IMT is stabilisized at 10% maximal inspiratory pressure. Proper information about the training protocol is given at the start of IMT in a Dutch users guide.
- 6 weeks of home-based peripheral muscle training program (The 5 Basic eXercise Program; 5 BX). Frequency is 5 days a week, 11 minutes a day. Patients are instructed at follow-up points and controlled by e-mail and telephone by one of the physiotherapists from the WKZ (H.J. Hulzebos).

The alternative protocol for the former participants in METC 11-084 will only consist of the six weeks home-based 5BX.

Study burden and risks

Up to date, exercise training and nutritional therapy are the cornerstone of CF care, which increased the median survival of patients with CF dramatically over the past decades.
As intervention all patients are asked to perform home-based IMT for 6 weeks, 5 times a week 11 minutes. Subsequent to IMT, patients undergo 6 weeks of 5BX, 11 minutes a day, 7 days a week. IMT* intensity is based on the patients* rate of perceived exertion, progression of intensity of the 5BX protocol is based on the ability of the participant to perform the exercises in 11 minutes.
No serious adverse effects are noted concerning IMT in children and young adults. Only one case of earache is found in a study concerning IMT in children. 5BX exercises are part of the physiotherapeutic care in children. For evaluation of intervention, several tests are performed and patients are asked to visit the hospital 5 times during the protocol. Tests are performed at baseline (t=0), after 6 weeks baseline measurements (t=6), after both interventions (t=12 and t=18) and after a six weeks wash-out period (t=24). At the hospital visits, a maximal exercise test is performed, three questionnaires are filled out, two functional physical performance tests (BOT2 and Timed up & go) are performed and strength tests, lung function and anthropometric measures are taken. At home, patients are asked to fill out a dairy concerning habitual physical activity and a training diary concerning compliance. Participants are also asked to wear an accelerometer at home to asses habitual physical activity.
The alternative protocol for the former participants in METC 11-084 will only consist of the six weeks home-based 5BX. Furthermore, beside spirometry and

anthropometry, the additional measurements for the alternative protocol are two CPET*s (one in a 31P-MRS scanner) after the training period. The other measurements of the original protocol will not be performed. Considering the alternative protocol, no risks are reported in literature concerning exercise in an MRS scanner. Progressive insight in the possible role of training induced altered muscle oxygen consumption or oxygen delivery in patients with CF will give a more fundamental explanation for possible results in the original study protocol. This insight will help to aim and institute interventions as exercise training.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

•Ambulant patients with CF

•Age: range from 12 to 18 years of age

Exclusion criteria

- Acute gastro-intestinal or pulmonary exacerbation (extra oral or intravenous antibiotics for the past four weeks) at inclusion.
- Oxygen saturation (SpO2) < 90% (without O2 supply)
- Ineligible to perform CPET
- not familiar with the Dutch language
- Pneumothorax

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-03-2010
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	28-07-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	31-08-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-04-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-06-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL27812.041.09