Effectiveness of Inspiratory Muscle Training on respiratory function and patient functioning in persons with Spinal Cord Injury

Published: 23-07-2009
Last updated: 04-05-2024

Evaluate the effectiveness of Inspiratory Muscle Training (IMT) during primary rehabilitation on pulmonary function and respiratory muscle strength in persons with SCI. Also, we will explore the long-term effectiveness on respiratory complications...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON33471

Source
ToetsingOnline

Brief title
Inspiratory Muscle Training in persons with Spinal Cord Injury

Condition

- Spinal cord and nerve root disorders

Synonym
spinal cord injury, spinal cord lesion

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Kinderfonds Adriaan Stichting

Intervention

Keyword: intervention, RCT, respiratory function, spinal cord injury

Outcome measures

Primary outcome

Pulmonary function, cough capacity and respiratory muscle force and endurance.

Secondary outcome

Respiratory complications and patient functioning

Study description

Background summary

Patients with high-level Spinal Cord Injury (SCI) suffer from disturbed function of respiratory muscles, resulting in decreased vital capacity (VC) and decreased ability to cough. Because of this, respiratory complications may occur, resulting in physical inactivity, decreased fitness, morbidity, disability, a delay in the process of recovery, and even mortality. An adequate and effective treatment of respiratory function in SCI may help prevent this cascade of deteriorating health consequences. Literature supports the potential of inspiratory muscle training, but more evidence about the effectiveness of this training, and about relevant relationships, determinants and consequences related to pulmonary function, inactivity and respiratory complications, is needed.

Study objective

Evaluate the effectiveness of Inspiratory Muscle Training (IMT) during primary rehabilitation on pulmonary function and respiratory muscle strength in persons with SCI. Also, we will explore the long-term effectiveness on respiratory complications and patient functioning.

Study design

Multi-centre single blind randomised control study.

Intervention

All subjects, in the intervention and control group, will receive the regular rehabilitation program and an added standardized educational module concerning general aspects of the respiratory function and risk of respiratory complications. The subjects in the intervention group will receive an 8-week training program focusing on inspiratory muscle strength. The training program exist of threshold IMT exercises, 30 minutes a day, 5 times a week, once a week supervised by a physical therapist (PT).

Study burden and risks

Subjects in the intervention group will perform IMT during 8 weeks, 30 minutes a day, 5 times a week. All subjects will receive a standardized educational module, consisting of 4 lessons of 30 minutes. Full measurements will take place before, directly after, and 8 weeks after the training period. In addition all subjects are asked weekly, between the first and third measurement, to fill in a short written questionnaire concerning respiratory complications, direct consequences and respiratory treatment. One year after discharge from the inpatient setting, subjects are invited back to the rehabilitation centre for a final and fourth measurement. The measurements cost 2 hours at a time. In the year post-discharge subjects are asked at three different moments to fill in a written questionnaire. This will cost 15 minutes each time. All subjects will possibly benefit from the structured attention and objective measurements of respiratory function. The subjects in the intervention group will possibly benefit from the intervention with improved respiratory function and decreased respiratory complications. There are no known risks for the intervention or measurements.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
3015 CE Rotterdam
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
3015 CE Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. recent Spinal Cord Injury
2. neurological classification: Thoracic 12 or above, ASIA A-D
3. decreased pulmonary function: FEV1<80% of predicted value
4. age 18-70 year

Exclusion criteria

1. progressive disease
2. psychiatric condition interfering with constructive participation
3. insufficient comprehension of the Dutch language
4. ventilator dependent
5. medically instable

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-09-2009
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Threshold IMT
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-07-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-02-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL28035.078.09