Inspiratory Muscle Training in persons with Spinal Cord Injury.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22046

Source
NTR

Brief title
N/A

Health condition

spinal cord injury; respiratory muscle function; respiratory complications.
dwarslaesie; respiratoire spierfunctie; respiratoire complicaties.

Sponsors and support

Primary sponsor: Erasmus MC, department of Rehabilitation Medicine, Rotterdam
Rijdnam revalidatiecentrum, Rotterdam
Source(s) of monetary or material Support: Stichting Rotterdams Kinderrevalidatie Fonds Adriaanstichting (KFA)

Intervention

Outcome measures

Primary outcome

1. Pulmonary function: FVC, FEV1, PEF;

2. Cough capacity: PCF;

3. Respiratory muscle function: PImax, PEmax;

4. Perceived respiratory function.

Secondary outcome

1. Respiratory symptoms;

2. Complications health related Quality of Life: SF-36.

Study description

Background summary

Rationale:

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.

Objectives:
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.

Study population:

Persons with SCI (n=40) and decreased pulmonary function, in an early stage of inpatient rehabilitation.

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).

Main study parameters:
Pulmonary function, cough capacity and respiratory muscle force and endurance.

Study objective

Inspiratory Muscle Training during primary rehabilitation will improve respiratory function in Spinal Cord Injury.
Respiratory Muscle Training will decrease the risk for long-term respiratory symptoms and complications in persons with spinal cord injury.

Study design

Measurements will be performed before training, directly after, 8 weeks after and one year after discharge from inpatient rehabilitation.

Intervention

Inspiratory Muscle Training.

Contacts

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Eligibility criteria

Inclusion criteria

1. Subjects with SCI, admitted for primary SCI at an inpatient rehabilitationcentre;

2. Motor level Thoracic 12 or higher;

3. ASIA A, B, C, or D;

4. Age 18 - 70;

5. Decreased pulmonary function; FEV1< 80% predicted value;

6. Written informed consent.

Exclusion criteria

1. Progressive disease;

2. Psychiatric condition;

3. Insufficient comprehension of the Dutch language;

4. Ventilator dependent or tracheotomy;

5. Medical instable.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2009
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-07-2009
Application type:	First submission

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	NL1811
NTR-old	NTR1921
Other	Erasmus MC, Rotterdam : 28035.078.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A