Inspiratory Muscle Training in persons with Spinal Cord Injury.

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22046

Bron
NTR

Verkorte titel
N/A

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus MC, department of Rehabilitation Medicine, Rotterdam
Rijdnam revalidatiecentrum, Rotterdam
Overige ondersteuning: Stichting Rotterdams Kinderrevalidatie Fonds Adriaanstichting (KFA)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Pulmonary function: FVC, FEV1, PEF;
2. Cough capacity: PCF;
3. Respiratory muscle function: PImax, PEmax;
4. Perceived respiratory function.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Inspiratory Muscle Training.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Progressive disease;

2. Psychiatric condition;

3. Insufficient comprehension of the Dutch language;

4. Ventilator dependent or tracheotomy;

5. Medical instable.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2009
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-07-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1811
NTR-old	NTR1921
Ander register	Erasmus MC, Rotterdam : 28035.078.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A