Effect of intensive exercise therapy with and without gravity compensation on upper extremity function in subjects with chronic cervical spinal cord injury.

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Gravity compensation in addition to intensive exercise therapy will result in a greater improvement in upper extremity function compared to intensive exercise practice without gravity compensation.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29035

Bron
Nationaal Trial Register

Verkorte titel
FzCompSCI

Aandoening

cervical spinal cord injury, upper extremity, gravity compensation, excersice therapy
cervicale dwarslaesie, bovenste extremiteit, zwaartekracht compensatie, oefentherapie

Ondersteuning

Primaire sponsor: Roessingh Research and Development b.v.
Overige ondersteuning: ministerie van EZ

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Functional outcome measurements:
* 2 times of the Van Lieshout Task
* 7 items of the Wolf Motor Function Task and the sf-QIF.

- Motor control parameters:
* EMG and movement tracking (Vicon)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

The consequences of Spinal Cord Injury (SCI) are diverse and complex. Subjects with a tetraplegia have impaired upper extremity function limiting the ability of individuals with cervical SCI to perform manual activities of daily living. Training of upper extremity function in tetraplegics is of great importance. Conventional training methods based on motor relearning principles require great physical effort from the patient which can limit the intensity of the training due to fatigue. New technological innovations in rehabilitation make it easier to control and report these variables. Studies have shown that by using a mechanical device to counteract the influence of gravity, active arm movements may be facilitated in stroke patients by reducing the required muscle activity to maintain a particular arm orientation. According to principles of motor relearning in stroke and SCI patients gravity compensation in addition to intensive exercise therapy could result in a greater improvement in upper extremity function.

Objective:

To investigate the effect of gravity compensation in combination with intensive exercise therapy on upper extremity function in subjects with SCI. Hypothesis: gravity compensation in addition to intensive exercise therapy will result in a greater improvement in upper extremity function compared to intensive exercise therapy alone.

Study design:

Cross-over, single blinded experimental design.

Study population:

Ten subjects with chronic SCI, between 18-65 years old with SCI level C5-C7, ASIA A-C.

Intervention:
A mechanical, passive device called Freebal will be used to counteract the influence of gravity on the upper extremity. An intensive exercise therapy program consisting of training of the upper extremity function by an occupational therapist for one and a half hours three times a week will be applied with and without gravity compensation for the duration of two periods of four weeks.

Main study parameters/endpoints:
The main study parameter is the change in upper extremity function using two VLT tasks, seven WMFT tasks and the sf-QIF. Change in motor control parameters will be measured using surface EMG and VICON.

Doel van het onderzoek

Gravity compensation in addition to intensive exercise therapy will result in a greater improvement in upper extremity function compared to intensive exercise practice without gravity compensation.

Onderzoeksopzet

The subjects were tested at the start of the training, after 4 and 8 weeks of training and finaly an follow-up measurement after 4 weeks.

Onderzoeksproduct en/of interventie

A mechanical, passive device called Freebal will be used to counteract the influence of gravity on the upper extremity. An intensive exercise therapy program consisting of training of the upper extremity function for 1.5 hours 3 times a week will be applied 4 weeks with and 4 weeks without gravity compensation.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 18 to 65;

2. Stable spinal cord injury with level C5-C7 and with American Spinal cord Injury; Association (ASIA) Impairment Scale A, B and C;

3. At least one year since time of injury;

4. Able to follow an intensive exercise program;

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Extreme shoulder pain;

2. Contractures upper extremity and/or spasticity preventing exercise therapy;

3. Cognitive/communicative impairments;

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2008
Aantal proefpersonen:	10
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	30-09-2008
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	NL1404
NTR-old	NTR1464
Ander register	Roessingh Research and Development : 08.05.6.3
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
Not applicable