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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29035

Source
Nationaal Trial Register

Brief title
FzCompSCI

Health condition

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

Sponsors and support

Primary sponsor: Roessingh Research and Development b.v.
Source(s) of monetary or material Support: ministerie van EZ

Intervention

Outcome measures

Primary outcome

- 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)

Secondary outcome

N/A

Study description

Background summary

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.

Study objective

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.

Study design

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.

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 for 1.5 hours 3 times a week will be applied 4 weeks with and 4 weeks without gravity compensation.

Contacts

Public
M. Jannink
[default]
The Netherlands

Scientific
M. Jannink
[default]
The Netherlands

Eligibility criteria

Inclusion criteria

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;

Exclusion criteria

1. Extreme shoulder pain;

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

3. Cognitive/communicative impairments;

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2008
Enrollment:	10
Type:	Actual

Ethics review

Positive opinion

Date:	30-09-2008
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	NL1404
NTR-old	NTR1464
Other	Roessingh Research and Development : 08.05.6.3
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

Not applicable