Preventieve armpositionering en elektrostimulatie bij CVA-patiënten.

No registrations found.

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

Summary

ID

NL-OMON20103

Source
Nationaal Trial Register

Brief title
PAESIS-trial

Health condition

Stroke (CVA)

Sponsors and support

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Source(s) of monetary or material Support: Fonds NutsOhra, project no. SNO-T-0702-072 (see www.fondsnutsohra.nl)

Intervention

Outcome measures

Primary outcome

1. Passive range of motion (PROM) of seven different arm movements will be assessed using a using a masked hydrogoniometer;

2. Shoulder pain will be assessed using the ShoulderQ.

Secondary outcome

1. The degree of difficulty the patient and his/her primary carer have with activities related to the hemiplegic (spastic) arm is assessed with the Leeds Arm Spasticity Impact Scale (LASIS);

2. Arm spasticity will be assessed using the Modified Tardieu Scale (MTS);

3. The 66-point arm section of the Fugl-Meyer Assessment (FMA) will be used to assess the ability to make selective movements of the hemiplegic arm;

4. The degree of shoulder inferior subluxation is clinically graded in (half) fingerbreadths palpable below the acromion process in both shoulders.

Study description

Background summary

Each year more than 41.000 people are struck by a stroke in the Netherlands. In more than 60% of the cases the hemiplegic arm remains without function. Disuse of the arm makes it prone to the occurrence of contracture formation and spasticity. This results in hemiplegic shoulder pain, motor impairments and activity limitations (e.g. cleaning the arm, dressing). Available evidence based single-modality treatments are not suitable for patients with poor motor performance, and severely affected patients are underrepresented in the research literature. Positioning procedures and electrical stimulation both seem best suitable for severely affected stroke patients and combining these treatment modalities may even be more efficacious. We hypothesize that the electrical stimulation intensifies the effect of the positioning procedure, resulting in slowing down of contracture formation, less hemiplegic shoulder pain, less restrictions in the stroke patient’s performance of activities of daily life, decreased levels of spasticity and prevention of subluxation.

Study objective

N/A

Study design

Measurements will be made at baseline, after 4 weeks (intermediate), after 8 weeks (outcome) and after 20 weeks (follow-up).

Intervention

The experimental group receives a standardised therapeutic procedure for the hemiplegic arm and simultaneous therapeutic electrical stimulation (TES) with a motor response (i.e. joint movement is elicited) of the external rotators of the shoulder and extensors of the forearm twice a day for 45 minutes on working days.

The control group receives a (sham) positioning procedure at half the available shoulder range of motion and simultaneous conventional transcutaneous electrical nerve stimulation (TENS) with a sensory response only (i.e. no movement is elicited) of the extensors of the forearm twice a day for 45 minutes on working days.

Contacts

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Eligibility criteria

Inclusion criteria

1. A first ever or recurrent stroke except subarachnoid hemorrhages;

2. Age above 18;

3. Between 2 and 8 weeks post-stroke;

4. An apparent paralysis / severe paresis of the involved upper limb.

Exclusion criteria

1. Any of the following contra indications for electrical stimulation:

A. Metal implants in the involved arm or shoulder;

B. Cardiac pacemaker;

C. Thrombosis;

D. (Thrombo)phlebitis;

E. Cancerous lesions;

F. Skin infections on forearm or shoulder blade;

G. Epileptic seizures six months previous to and since the stroke;

H. Pregnancy and myasthenia gravis/myotonia.

2. Pre-existent impairments of the affected arm (e.g. peripheral neuropathy, frozen shoulder);

3. The ability to make selective movements of the hemiplegic arm (more than 18 points on the Fugl-Meyer Assessment arm score);

4. Severe cognitive deficits and/or severe language comprehension difficulties (more than one of four questions wrong on the verbal items of the AbilityQ).

Study design

Design

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

Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-08-2008
Enrollment:	38
Type:	Actual

Ethics review

Positive opinion

Date:	07-04-2009
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	NL1650
NTR-old	NTR1748
Other	Medical Ethical Committee University Medical Center Groningen / CCMO : 2008.107 / ABR no. 22402.042.08
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A