Preventieve armpositionering en elektrostimulatie bij CVA-patiënten.

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N/A

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

Samenvatting

ID

NL-OMON20103

Bron
NTR

Verkorte titel
PAESIS-trial

Aandoening

Stroke (CVA)

Ondersteuning

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Overige ondersteuning: Fonds NutsOhra, project no. SNO-T-0702-072 (see www.fondsnutsohra.nl)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

N/A

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	11-08-2008
Aantal proefpersonen:	38
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

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

Resultaten

Samenvatting resultaten
N/A