The influence of shock wave therapy on function improvement of upper limb muscles after stroke.

Gepubliceerd: 08-10-2013 Laatst bijgewerkt: 13-12-2022

Authors hypothesized that the physical extracorporeal shock wave (ESW) stimulation will decrease the resting muscle activity of paralysed forearm muscles, reducing the degree of spasticity in surface electromyography examination as well as Modified...

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

Samenvatting

ID

NL-OMON20785

Bron
Nationaal Trial Register

Verkorte titel
ESW - extracorporeal shock wave

Aandoening

Extracorporeal shock wave stimulation, biophysical mechanisms, electromyography, thermography, muscles spasticity, ischemic stroke.

Ondersteuning

Primaire sponsor: University of Medicine
Overige ondersteuning: National Science Centre; ul. KrÃ³lewska 57, 30-081 KrakÃ³w, Poland; phone: +48 12 341 90 00; email: biuro@ncn.gov.pl;

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The surface electromyography Noraxon MyoSystem 1400A (Noraxon, USA) will be used to obtain reliable analysis of the muscle bioelectrical activity, expressed as the resting muscle tone of affected muscles. Mean rest muscle tension, expressed in microvolts [Î¼V], will be recorded, determined as the arithmetic mean value of muscle tension in the examined group of muscles for the entire period of measurement per time unit [s].
The infrared camera MobIR M8 (Test-Therm, Poland) will be used to register thermal phenomena at the vascular level in examined muscles, as well as to visualize changes in local temperature distribution of stimulated tissues. The mean value of the tissue heat level within examined muscles will be determined, taken as the arithmetic mean of each isotherm within the whole area of measurement, expressed in Celsius degrees [Â°C]. The maximal and minimal temperature of the examined area also will be established, taken as a set of points with the highest level of heat within the area of measurement, expressed in Celsius degrees [Â°C].

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

Authors hypothesized that the physical extracorporeal shock wave (ESW) stimulation will decrease the resting muscle activity of paralysed forearm muscles, reducing the degree of spasticity in surface electromyography examination as well as Modified Ashworth Scale (MAS). ESW stimulation will also contribute to enhance of average and maximum temperature of examined tissues as a result of improved trophic condition at the microcirculation level in thermal imaging.

Onderzoeksopzet

In the first stage, all the initial measurements will be performed immediately before a single application of ESW, and directly after its completion. In the second stage, final measurements will be performed after 1 and 24 hours following stimulation.

Onderzoeksproduct en/of interventie

Study group: radial ESW stimulation on bellies of carpal flexor radialis and carpal flexor medialis muscles within spastic paresis. ESW parameters: numer of shots (S) = 1500,

pressure (P) = 1.5 bar, energy density (E) = 0.10 mJ/mm2, frequency (f) = 10 Hz, applicator diameter (d) = 15 mm.
Placebo group: sham ESW without active biologically component will be applied, preserving appropriate duration, imitating the active stimulation. The special polyethylene cap energy damping filled with sponge will be used.

Contactpersonen

Publiek

Department of Nervous System Diseases, University of Medicine in Wroclaw, ul. Bartla 5, 51-618 Wroclaw, Poland;
Robert Dymarek
Warsaw
Poland
+48 71 784 18 39

Wetenschappelijk

Department of Nervous System Diseases, University of Medicine in Wroclaw, ul. Bartla 5, 51-618 Wroclaw, Poland;
Robert Dymarek
Warsaw
Poland
+48 71 784 18 39

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Ischemic stroke episode > 9 months previously, level of spasticity in MAS > 1, no antispastic interventions (surgical, pharmacological, rehabilitation), no ESW contraindications, agreement of participant.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Ischemic stroke episode < 9 months previously, deifferent ethiology of stroke, level of

spasticity in MAS < 1, surgical antispastic interventions (rhizotomy, neurectomy, cordectomy, myotomy), antispactic pharmacotherapy (Diazepam, Baclofen, Dantrolene, Tizanidine, Botuline), antispastic rehabilitation, present contraindications to ESW stimulation (pregnancy, cancer, local tumors, coagulation disorders, acute and recurrent inflammatory states, pacemakers and other electronic implants), resignation during research, non-agreement of participant.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	02-08-2013
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-10-2013
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	NL4035
NTR-old	NTR4201
Ander register	GR-783/NCN/2012 : UMO-2011/03/N/NZ7/00327
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A