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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20785

Source
Nationaal Trial Register

Brief title
ESW - extracorporeal shock wave

Health condition

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

Sponsors and support

Primary sponsor: University of Medicine
Source(s) of monetary or material Support: National Science Centre; ul. KrÃ³lewska 57, 30-081 KrakÃ³w, Poland; phone: +48 12 341 90 00; email: biuro@ncn.gov.pl;

Intervention

Outcome measures

Primary outcome

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].

Secondary outcome

The Modified Ashworth Scale will be use to assess clinical changes in muslces spaticity level, before and after ESW stimulation or placebo intervention.

Study description

Background summary

N/A

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-08-2013
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

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

Study results

Summary results
N/A