Functional added value of shockwave therapy in persons with a spinal cord injury and spasticity: a multiple single case experimental design study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON55078

Source
ToetsingOnline

Brief title
Shockwave therapy in persons with a spinal cord injury and spasticity

Condition

- Muscle disorders
- Spinal cord and nerve root disorders

Synonym
spasticity, spinal cord injury

Research involving
Human

Sponsors and support

Primary sponsor: Adelante Zorggroep
Source(s) of monetary or material Support: Adelante Zorggroep

Intervention

Keyword: shockwave therapy, single case experimental design, spasticity, spinal cord injury

Outcome measures

Primary outcome

An improvement in the performance of specific ADL tasks for the upper or lower extremities is measured using the Goal attainment Scaling (GAS).

Secondary outcome

Secondary outcome measures are: active range of motion (AROM), passive range of motion (PROM), 10 meter walk test (10MLT), pain perception in the treatment area (VAS) and the short version of the Van Lieshout arm dexterity test for Tetraplegia (VLT-sf) that will be reported descriptively.

Study description

Background summary

About 65-78% of people with spinal cord injury develop spasticity. In general, 27-40% of the spinal cord injury population find spasticity problematic and functionally impairing. In (multi) focal spasticity, Botulinum toxin (BoNT), peripheral nerve blocks and surgery are used. A new application is extracorporeal shockwave therapy (ESWT). This therapy is considered a safe, effective, practical and non-invasive method to reduce spasticity without causing muscle weakness or unpleasant experiences. Studies in recent years show that ESWT is a safe way of treating people with (multi) focal spasticity. These studies were done in people with Cerebral Palsy (CP), Cerebro Vascular Accident (CVA) and Multiple Sclerosis (MS). ESWT has not yet been used in people with spinal cord injury.

Study objective

Aim of the study is to ascertain the order of magnitude to which ESWT may improve the performance of specific activities of daily living (ADL), measured by Goal Entertainment Scaling (GAS) in people with spinal cord injury and spasticity in the chronic phase.

Study design

In this study, a multiple single case experimental design (A-B-A) with a randomized intervention starting point is used.

Intervention

During the intervention period, 5 patients are treated in the wrist / hand region and 5 patients in the calf region. In a time period of 3 weeks, each patient receives 3 ESWT treatment sessions of (on average) 10 minutes, with an intermediate period of at least 6 days.

Study burden and risks

Administration of the ESWT may reduce the symptoms of calf or wrist / hand spasticity, enabling the patient to perform several ADL tasks better. A rehabilitation physician assesses the medical indication for the administration of ESWT. While participating in the study, the patient should not receive BoNT or change spasm medications (dose). Also, the patient must undergo some measurements that would be less frequent without participating in this study. These measuring instruments belong to the *standard* measuring instruments of physiotherapy or rehabilitation. Studies in recent years show that ESWT is a safe way of treating people with (multi) focal spasticity. These studies were done in people with Cerebral Palsy (CP), Cerebro Vascular Accident (CVA) and Multiple Sclerosis (MS). However, such study has not yet been performed in people with a spinal cord injury. It is a non-invasive method of treatment without muscle weakness or unpleasant experiences. The ESWT is only applied in the chronic phase after a spinal cord injury, so the ESWT does not hinder the (prior) rehabilitation process.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Diagnosed with a spinal cord injury (ASIA / AIS score C or D) for more than 6 months.
* Spastic paresis / paralysis in the calf or wrist / hand region (MAS score * 1+).
* Age *18 years.
* No additional orthopedic, rheumatological or neurological co-morbidity that can obscure the answer to the research question.
* No cognitive problems that hinder the participant's understanding of the assignments during the research.
* Adequate knowledge of the Dutch language, i.e. being able to understand the (measurement) assignments.
* Being able to walk 10 meters; regarding ESWT of the calf region.
* Being able to, at least, operate an electric wheelchair with the arm in question; regarding ESWT of the wrist / hand region.

Exclusion criteria

* Pregnancy.
* Tumor.
* Osteoporosis.
* Thrombosis.

* Polyneuropathy in diabetes.
* Neuromuscular disorders.
* Metal implants in the area to be treated.
* Infection or inflammation of the skin area to be treated.
* Oral anticoagulation medication like coumarine derivatives, DOAC*s or NOAC*s.
* administration of a BoNT injection in the area to be treated within the past 4 months.
* Cortisone therapy up to 6 weeks before the first treatment.
* Pacemaker or electronic implants.
* An intrathecal Baclofen pump.
* Presence of contractures where a reduction in spasticity does not show an improvement in passive range of motion (PROM) in the area to be treated
* No informed consent.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-12-2020
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Storz Masterpuls MP100 Ultra
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	25-08-2020
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	09-04-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
CCMO	NL73561.015.20
Other	Studie zal na METC goedkeuring nog bij NTR geregistreerd worden