

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The effect of EXtracorporeal shock wave therapy on plantar spasticity following cerebral stroke: A randomized controlled trial

Protocol summary

Summary

The aim of this study is to evaluate the therapeutic effects of shock wave on the spasticity of lower limbs in patients with cerebral stroke. In this single blind clinical trial (Another clinician who was not aware of the patients categorization performed the measurements), 28 cerebral stroke patients from both genders will enter the study according to the inclusion and exclusion criteria. The patients will be divided into two groups of intervention and control (each 14). The intervention group will receive one shock wave session a week for three weeks. The shock wave focus probe will be placed on the medial and lateral head junction of Gastrocnemius and 1500 shocks with 4 HZ in frequency and 0.1 mJ/cm² in intensity will be administered. Calves muscles stretching exercise will also be performed. The control group will only receive stretching exercises. The patients spasticity grade will be evaluated according to Modified Ashworth scale. The pain scale will be evaluated by VAS score. The Lower extremity functional index questionnaire will be used for evaluating the lower limb function. The clonus degree and ankle range of motion also will be checked. The time required for six meter walking will be assessed using by TUG test. All the mentioned tests in both groups will be evaluated at the base line, 1th, 3d, 12th week and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010225803N1**

Registration date: **2016-08-05, 1395/05/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-05, 1395/05/15

Registrant information

Name

Maryam Mellat Ardekani

Name of organization / entity

MD, Resident of Physical medicine and rehabilitation

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Financial resources of the Isfahan University of Medical Science

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2016-01-19, 1394/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of EXtracorporeal shock wave therapy on plantar spasticity following cerebral stroke: A randomized controlled trial

Public title

The effect of shock wave therapy on spasticity of post stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria(age between 18-80; at least one month after CVA; concept of information consent; spasticity score in Modified Ashworth scale in 2-4 Exclusion criteria: (liver failure; pregnancy; History of malignancy; ankle contracture; severe inflammation in treated region; history of Botulinum injection in Gastrocnemius muscle in the past 6 months or phenol and alcohol; unwillingness to continue participating in the study.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Science

Street address

Isfahan University of Medical Science, Hezar jirib Avenue

City

Isfahan

Postal code

Approval date

2014-11-26, 1393/09/05

Ethics committee reference number

394191

Health conditions studied

1

Description of health condition studied

stroke

ICD-10 code

I64

ICD-10 code description

Stroke, not specified as haemorrhage or infarction

2

Description of health condition studied

spasm

ICD-10 code

R25.2

ICD-10 code description

Cramp and Spasm

Primary outcomes

1

Description

Modified Ashworth scale

Timepoint

Base line, 1, 3, 12 weeks after beginning of intervention in control and intervention groups.

Method of measurement

By examiner

2

Description

Clonus measurment

Timepoint

Base line, 1, 3, 12 weeks after beginning of intervention in control and intervention groups.

Method of measurement

Examiner

3

Description

Time Up and Go test

Timepoint

Base line, 1, 3, 12 weeks after beginning of intervention in control and intervention groups.

Method of measurement

Chronometer

4

Description

Ankle range of motion

Timepoint

Base line, 1, 3, 12 weeks after beginning of intervention in control and intervention groups.

Method of measurement

Goniometer

5

Description

Pain

Timepoint

Base line, 1, 3, 12 weeks after beginning of intervention in control and intervention groups.

Method of measurement

VAS

6

Description

Lower limb function

Timepoint

Base line, 1, 3, 12 weeks after beginning of intervention in control and intervention groups.

Method of measurement

Lower limb functional scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The Intervention group will receive one shock wave session a week for three weeks. The shock wave focus probe will be placed on the medial and lateral head junction of Gastrocnemius and 1500 shocks with 4HZ intensity and 0.1 mJ/CM2 will be administered. Calves muscle stretching exercises will also be performed.

Category

Rehabilitation

2

Description

In Control group, only Gastrocnemius muscles stretching exercise will be done in home.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

kashani Hospital

Full name of responsible person

DR. Maryam Mellat Ardakani, Resident of Physical medicine and rehabilitation

Street address

Kashani Hospital, Kashani Avenue, Isfahan, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mansour Siavash

Street address

Vice chancellor for research, Isfahan University of Medical Sciences, Hezar Jerib Avenue, Isfahan

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research of Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Science

Full name of responsible person

Maryam Mellat Ardekani

Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty