Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of EXtracorporal shock wave therapy on plantar spasticity fallowing cerbral 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 in to 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

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Maryam Mellat Ardekani
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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 EXtracorporal shock wave therapy on plantar spasticity fallowing cerbral 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 begining of intervention in control and intervention groups.
Method of measurement
By examiner

2

Description
Clonus measurment
Timepoint
Base line, 1, 3, 12 weeks after begining 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 begining 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 begining of intervention in control and intervention groups.
Method of measurement
Goniometer

5

Description
Pain
Timepoint
Base line, 1, 3, 12 weeks after begining of intervention in control and intervention groups.
Method of measurement

VAS

6

Description
Lower limb function
Timepoint
Base line, 1, 3, 12 weeks after begining of intervention in control and intervention groups.
Method of measurement
Lower limb functional scale questionaire

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 stertching 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
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Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Isfahan University of Medical Siences
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 Siences
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
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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