Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of shockwave therapy on pain of patient with post stroke hemiplegic shoulder pain

Protocol summary

Study aim
Determine the therapeutic effect of shockwave therapy. Reducing pain and improving patient performance in patients with shoulder pain after a stroke in 1397.

Design
A clinical trial with a control group, with parallel groups, double blind, randomized

Settings and conduct
This is a RCT randomized clinical trial that was conducted during 1397 in physiotherapy and rehabilitation clinics affiliated to Isfahan University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Satisfaction to participate in the study؛ Age group 20-80 years؛ At least 3 months have passed since the stroke occurred؛ Shoulder pain and shoulder paralysis have started after ischemic stroke؛ The severity of the shoulder pain is based on the vas criterion of at least 4 or more for at least 3 months؛ Exclusion criteria: Not being able to express the severity of pain Surgical history on the shoulder؛ Use of oral hives 3 days before the study Intraocular infusion or other interventions affecting shoulder in the past month؛ Taking high dose warfarin (INR above 4)؛ Trauma history on shoulders؛ Patients receiving a cardiac pacemaker؛ Moderate to severe depression؛ crps based on patient examination؛ History of shoulder pain before a stroke؛ Based on the examinations, no mechanical causes for pain should be noted.

Intervention groups
Patients are divided into two groups of intervention and control for Shockwave. The number of meetings is 5 sessions, which includes 3 focus sessions with weekly intervals and 5 radial sessions with intervals of two days per week. The protocol of the case and control groups were similar, only in the control group, the Sham method was used, except that they would receive zero energy.

Main outcome variables
Severe shoulder pain؛ Severe shoulder pain؛ The range of shoulder motion؛ Time to start shoulder pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171030037093N9**
Registration date: **2019-05-06, 1398/02/16**
Registration timing: **prospective**

Last update: **2019-05-06, 1398/02/16**
Update count: **0**

Registration date
2019-05-06, 1398/02/16

Registrant information

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Name of organization / entity
Shahrekord University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-01, 1398/03/11

Expected recruitment end date
2020-01-31, 1398/11/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of shockwave therapy on pain of patient with post stroke hemiplegic shoulder pain

Public title
Evaluation of the effect of shockwave therapy on pain of patient with post stroke hemiplegic shoulder pain

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
Satisfaction to participate in the study Age group 20-80 years At least 3 months have passed since the stroke occurred. Shoulder pain and shoulder paralysis have started after ischemic stroke. The severity of the shoulder pain is based on the vas criterion of at least 4 or more for at least 3 months.

Exclusion criteria:
Not being able to express the severity of pain Surgical history on the shoulder Use of oral hives 3 days before the study Intraocular infusion or other interventions affecting shoulder in the past month Taking high dose warfarin (INR above 4) Trauma history on shoulders Patients receiving a cardiac pacemaker Moderate to severe depression crps based on patient examination History of shoulder pain before a stroke Based on the examinations, no mechanical causes for pain should be noted.

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly assigned to one of the two groups by selecting the cards named A and B.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the principal executor is considered to be medical doctors who are fully aware of the goals of the study and the types of treatments. Patients will not be aware of statistical research goals and how to compare treatments. However, they are fully aware of the fact that they are treated with different treatments in one of the two groups and that they receive treatment for their illness and have been studying satisfactorily. Patients will not be aware of shock or vision shock therapy. The counselor for statistics and information analytics, about treatment (shockwave and shock sham) and the name of the patients is not known.

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 Sciences

Street address
Isfahn University of Medical Sciences, Hezar jarib st, Isfahan

City
Isfahan

Province
Isfehan

Postal code
7346181746

Approval date
2019-01-07, 1397/10/17

Ethics committee reference number
IR.MUI.MED.REC.1398.035

Health conditions studied

1

Description of health condition studied
Shoulder pain

ICD-10 code
M25.51

ICD-10 code description
Pain in shoulder

Primary outcomes

1

Description
Severe shoulder pain

Timepoint
The beginning of the study, the end of treatment, and weeks 4 and 8 after treatment

Method of measurement
Vas questionnaire

2

Description
Shoulder performance

Timepoint
The beginning of the study, the end of treatment, and weeks 4 and 8 after treatment

Method of measurement
Examination and questionnaire

3

Description
The range of shoulder motion
Timepoint
The beginning of the study, the end of treatment, and weeks 4 and 8 after treatment
Method of measurement
Goniometer

4

Description
Time to start shoulder pain
Timepoint
The beginning of the study, the end of treatment, and weeks 4 and 8 after treatment
Method of measurement
Information Form

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Under treatment with shockwave, the number of sessions is 5 sessions, which consists of 3 sessions of focus with intervals and 5 radial sessions with intervals of two days per week. The SHAKEVIEW protocol is in this form. Shockwave focus is expressed as the number of shocks of 1,000 at any point with a J2 / 0-3 / 0 energy of ZH 4 and a radial to 1000 shocks per point with an energy of 1.33 j3 and a frequency of 15Hz.
Category
Treatment - Devices

2

Description
Control group: Sham treatment was used with zero energy
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Physiotherapy and Rehabilitation Clinics of Isfahan University of Medical Sciences
Full name of responsible person
Shila Haghighat
Street address
Office of Physical Medicine and Rehabilitation, Al-Zahra Educational Center, ,Sofe St., Isfahan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shila Haghighat
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work

Physical Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Information about the main outcome can be shared.

When the data will become available and for how long
Start the access period 4 months after publishing the results

To whom data/document is available
Researchers working in academia

Under which criteria data/document could be used
Use data to complete clinical trial studies

From where data/document is obtainable
Department of Physical Medicine and Rehabilitation

What processes are involved for a request to access data/document
After the investigation of researcher request and presentation of required documents will be accessible.

Comments