

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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

Name

Sadra Ansaripour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 31 3650 3487

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st_ansari.s@skums.ac.ir

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

Isfahan

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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haghighatshil@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ziba Farajzadegan

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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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Department of Physical Medicine and Rehabilitation,
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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