

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effects of Extra corporeal shock wave therapy on pain and disability of chronic low back pain patients

Protocol summary

Study aim

1. Determine and compare the mean and median VAS score before treatment between the comparison and intervention groups
2. Determination and comparison of mean and median VAS score one and three months after treatment between comparison and intervention groups
3. Determination and comparison of pre-treatment disability score between comparison and intervention groups
4. Determine and compare the disability score one and three months after treatment between the comparison and intervention groups
5. Comparison of mean and median VAS score before and one and three months after treatment in the comparison group
6. Comparison of disability score before and one and three months after treatment in comparison group

Design

A randomized controlled clinical trial with parallel groups, without blinding

Settings and conduct

This study was performed in patients with chronic low back pain referred to physical medicine clinic of Isfahan University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: 1. People over 5 years old with low back pain 2.2. Lack of back pain for more than 2 weeks and no treatment in the last month. 3. Patients have never had lumbar surgery.

Intervention groups

Patients included in this study were randomly divided into two groups of intervention and comparison. One group of patients is treated with drug and exercise and shockwavesham, and the other group is treated with shockwave in addition to medicine and exercise. We use 4Hz frequency and 0.15 joule energy is applied to the painful areas of the gluteal and paraaspinal muscles. This modality is administered once a week for four weeks to the patient.

Main outcome variables

Mean VAS score; disability score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191021045171N1**

Registration date: **2019-12-04, 1398/09/13**

Registration timing: **retrospective**

Last update: **2019-12-04, 1398/09/13**

Update count: **0**

Registration date

2019-12-04, 1398/09/13

Registrant information

Name

Mitra ramezany

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 9135

Email address

mitra.ramezany@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-06-01, 1396/03/11

Expected recruitment end date

2018-03-01, 1396/12/10

Actual recruitment start date

2017-06-01, 1396/03/11

Actual recruitment end date

2018-03-01, 1396/12/10

Trial completion date

2018-03-01, 1396/12/10

Scientific title

The effects of Extra corporeal shock wave therapy on pain and disability of chronic low back pain patients

Public title

Extra corporeal shock wave therapy for chronic Low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1.Low back pain for more than 12 weeks and no treatment in the last month, 2.Patients have never had lumbar surgery, 3.Do not have mental or cognitive illness, 4.Don't be pregnant, 5.No structural spine diseases, 6.No current fracture or history of vertebral fracture, 7.Absence of spinal cord tumor, 8.Absence of vertebral or intervertebral disc infections, 9.Absence of inflammatory diseases such as rheumatoid arthritis, 10.Absence of nerve symptoms caused by intervertebral disc herniation and 11.Do not have a coagulation disorder.

Exclusion criteria:

Age

From 18 years old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 56

Actual sample size reached: 50

Randomization (investigator's opinion)

Randomized

Randomization description

The simple randomization method will be randomly divided into intervention and comparison groups using Random allocation software.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

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

Isfahan University of Medical Science, Hezarjrib

Street, Isfahan city

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2017-02-28, 1395/12/10

Ethics committee reference number

IR.MUI.REC.1395.3.978

Health conditions studied

1

Description of health condition studied

Chronic low back pain and disability

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Chronic lower back pain

Timepoint

Before and after treatment

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group are treated with medicine, exercise and shock wave therapy. Shock wave therapy sessions are four (weekly) and in each session patients are received 1500 shocks with 4 Hz frequency on Gluteal and Paraspinal muscles.

Category

Rehabilitation

2

Description

Control group: Patients in this group are treated with medicine, exercise and shock wave sham therapy. Shock wave sham therapy sessions are four (weekly) and in each session patients are received sham shock waves on Gluteal and Paraspinal muscles.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Mitra Ramazani

Street address

Alzahra hospital, Shohadaye Sofeh Street, Isfahan city

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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Isfahan University of Medical Science, Hezarjrib Street, Isfahan City

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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

Mitra Ramezany

Position

Specialist physician

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Parisa Taheri

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mitra Ramezany

Position

Non-academic specialist physician

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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

Only part of the data, such as information about the original outcome or the like, can be shared.

When the data will become available and for how long

2020

To whom data/document is available

Everyone

Under which criteria data/document could be used

Mann-Whitney Repeated Repeated Measures of ANOVA tests were performed

From where data/document is obtainable

Through the responsible author

What processes are involved for a request to access data/document

6 to 12 months

Comments