Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effects of Extra corporeal shock wave therapy on pain and disability of chronic low back paining 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 paining 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
Isfehan
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
City
Isfahan
Province
Isfehan
Postal code
817746-73461
Phone
+98 31 3668 0048
Email
mitra.ramezany@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
Street address
Isfahan University of Medical Science, Hezarjrib Street, Isfahan City
City
Isfahan
Province
Isfehan
Postal code
817746-73461
Phone
+98 31 3668 0048
Email
research@mui.ac.ir

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
Street address
Isfahan University of Medical Sciences, Hezarjrib Street, Isfahan City
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 0048
Email
mitra.ramezany@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Parisa Taheri
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Physical Medicine
Street address
Isfahan University of Medical Sciences, Hezarjrib Street, Isfahan City
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 0048
Email
prs-taheri@yahoo.com

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
Street address
Isfahan University of Medical Science, Hezarjrib Street, Isfahan City
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3792 9135
Fax
Email
Mitra.ramezany@gmail.com

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