Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of Exercise therapy with and without complementary shock wave therapy on the pain and range of motion in patients with frozen shoulder

Protocol summary

Study aim

The effectiveness of exercise therapy with and without complementary shock wave therapy on the pain and range of motion in patients with frozen shoulder

Design

Clinical trials with a control group and an experimental group will be performed in both blind and random directions. Randomization will be done by computer numbers

Settings and conduct

Experimental group received six sessions of 45 to 60 minutes (18 sessions) of exercise for six weeks each week, and from week 3 to 6 of training, will receive exercise therapy with shock wave (1 in 5 days until 4 sessions). Positive control group Includes basic exercises (Joint play movements, stretching exercises, manipulation and PNF exercises, range of motion exercises and strength exercises) for six weeks, from week 3 on wards to weeks 6, while the shock wave device will be turn off and will be put on the patient's shoulder for a similar time. Patients and investigator and data analyst will be blind to the study

Participants/Inclusion and exclusion criteria

Study entry requirements: Having symptoms and signs of frozen shoulder disease for at least 3 months; Frozen shoulder disease according to orthopedic specialist diagnosis; Significant loss of shoulder joint mobility in active and passive motion; Nocturnal pain and daily activity in the shoulder joint; Study no entry requirements: Having a history of illness and underlying injuries affecting the frozen shoulder such as fracture, dislocation, joint instability; Having a history of neuromuscular skeletal disease; Rotator Cuff Muscle Tear; History of previous surgeries; History of taking any medication or painkiller and Use of therapeutic measures for frozen shoulder problems

Intervention groups

Control group: They will do a exercise therapy program. Experimental group: they will be treated with exercise therapy and shock wave.

Main outcome variables

Improves shoulder pain and range of motion

General information

Reason for update

Acronym

ESWT

IRCT registration information

IRCT registration number: **IRCT20200326046866N1**
Registration date: **2020-10-06, 1399/07/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-06, 1399/07/15**
Update count: **0**

Registration date

2020-10-06, 1399/07/15

Registrant information

Name

Alireza Rouhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3557 9744

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-01, 1399/07/10

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of Exercise therapy with and without complementary shock wave therapy on the pain and range of motion in patients with frozen shoulder

Public title

The effectiveness of Exercise therapy and complementary shock wave therapy on improving the situation in patients with frozen shoulder

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

with symptoms and signs of frozen shoulder disease for at least 3 months with Frozen shoulder disease according to orthopedic specialist diagnosis Significant loss of shoulder joint mobility in active and passive motion Nocturnal pain and daily activity in the shoulder joint Age range 40 to 60 years

Exclusion criteria:

history of illness and underlying injuries affecting the frozen shoulder such as fracture, dislocation, joint instability history of neuromuscular skeletal disease Rotator Cuff Muscle Tear History of previous surgeries History of taking any medication or painkiller and Use of therapeutic measures for frozen shoulder problems

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **13**

In case group: 13 patients with frozen shoulder and at least 3 months duration of symptoms without any comorbid disorders who will be treated with Exercise therapy and shock wave. Control group: In case group: 13 patients with frozen shoulder and at least 3 months duration of symptoms without any comorbid disorders who will be treated with physiotherapy

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups A and B using computer randomization (using Excel program). This arrangement is written in envelopes and Put in a box and When selecting patients, they are treated according to this sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients ,investigator and data analyst will be blind to the study But consequence assessor and data supervisor committee will be aware of study. Patients: shock wave probe are gonna applied in both groups But in the control group it will be in off mode. Investigator and data analyst: they are going to analyze the data without any information about patients groups.

Placebo

Used

Assignment

Parallel

Other design features

In the control group, patients will receive exercise therapy for up to six weeks. but In the intervention group, the treatment protocol is performed in such a way that patients do exercise therapy for up to three weeks. From week three onward, they will be treated with exercise therapy (on days when they do not exercise therapy) for up to six weeks with a shock wave.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz Universityy of Medical Sciences

Street address

Ashpaz bashi Restaurant, front of Tareh Bar Square, Sheikh Shaltout Blvd

City

urmia

Province

West Azarbaijan

Postal code

5714965314

Approval date

2020-09-14, 1399/06/24

Ethics committee reference number

IR.TBZMED.REC.1399.640

Health conditions studied

1

Description of health condition studied

Frozen Shoulder

ICD-10 code

M75.0

ICD-10 code description

Adhesive capsulitis of shoulder

Primary outcomes

1

Description
Improve pain
Timepoint
Before starting the intervention- Six weeks after the intervention
Method of measurement
Visual Analogue Scale - Constant Murley Score

2

Description
Improve range of motion
Timepoint
Before starting the intervention- Six weeks after the intervention
Method of measurement
Shoulder Pain And Disability Index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: It will use a shock wave therapy device with the specifications of ROSETTA the CR technology made in South Korea. The treatment protocol will be such that the person is sitting in the shock wave group with the shoulder away from the center with the elbow curve at an angle of 45 degrees and the arm at rest. Shock waves will shine on the sensitive points near the Rotator cuff joint in the small protrusion of the bone, below the tip of the shoulder. Shock wave will be performed once every five days for 4 consecutive weeks and in each session 3000 shocks with a frequency of 10 Hz.
Category
Rehabilitation

2

Description
Control group: An exercise therapy program is offered for six weeks and three sessions each week (between 45 and 60 minutes) that From week three onward, they receive the same treatment as the experimental group for up to six weeks, While the shock wave device is off and is placed on the patient's shoulder at the same time.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Behbood Physiotherapy Clinic
Full name of responsible person
Dr Amin Abdali
Street address
Ashpaz bashi Restaurant, In front of Tareh Bar Square, Sheikh Shaltout Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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Phone
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herasat@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Dr Alireza Rouhani
Position
Associate professor
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is 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
Not applicable
Title and more details about the data/document
In case of journal editor requesting
When the data will become available and for how long
After submission until article publication
To whom data/document is available
Editors and reviewers
Under which criteria data/document could be used
For the next studies
From where data/document is obtainable
Corresponding author
What processes are involved for a request to access data/document
Writing a Email
Comments