

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 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)

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+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 University of Medical Sciences

Street address

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

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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

Dr Mohammad Samiyy

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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

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

Subspecialist

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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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