

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Comparison of application of the Radial Vs. focused probes of extracorporeal shockwave therapy on Pain, ROM, and function in patients with adhesive capsulitis

Protocol summary

Study aim

To compare application of the radial vs. focused probes of extracorporeal shockwave therapy on pain, range of motion, and function in patients with adhesive capsulitis

Design

Forty patients with adhesive capsulitis are divided into two intervention groups (radial and focused shockwave) by simple randomization using a sealed envelope. The study is double blinded and the third phase.

Settings and conduct

Adhesive capsulitis (AC) is an inflammatory disorder that causes shoulder stiffness and pain. Shockwave therapy is widely used for treatment of AC, although to our knowledge no research has directly compared the effectiveness of focused shockwave and radial shockwave on pain, range of motion, and function of patients with AC. This study will be performed on patients referred to the outpatient physiotherapy clinic of the School of Rehabilitation. The study will be double blinded. Patients have no knowledge about the type of the probe used and the coding to the evaluation forms will be used for blinding.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Participants above the age of 18 years old with definitive diagnosis of sub-acute and chronic unilateral adhesive capsulitis Exclusion Criteria: History of fractures, surgery and inflammatory arthropathy in shoulder, cancer, tumors, bleeding disorders, and Aspirin intake during the last 3 days

Intervention groups

Both intervention groups will receive routine treatments including infrared, ultrasound, supervised and home exercises. One of the intervention groups will receive the radial shockwave and the other, the focused shockwave.

Main outcome variables

Pain at rest and during exercise, range of motion, scapular dyskinesia, DASH (Disabilities of the arm,

shoulder, and hand) score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210214050356N3**

Registration date: **2022-03-21, 1401/01/01**

Registration timing: **prospective**

Last update: **2022-03-21, 1401/01/01**

Update count: **0**

Registration date

2022-03-21, 1401/01/01

Registrant information

Name

Sara Fereydounnia

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-06-05, 1401/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of application of the Radial Vs. focused probes of extracorporeal shockwave therapy on Pain, ROM, and function in patients with adhesive capsulitis

Public title

Efficacy of mechanical wave in treatment of adhesive capsulitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Participants with sub-acute and chronic adhesive capsulitis (AC) A history of at least 4 months The diagnosis was confirmed clinically by physical examination The presence of AC on one side The age above 18 years old

Exclusion criteria:

Compound shoulder injuries Shoulder fractures Previous shoulder surgery Cancer Tumors Inflammatory Arthropathies of the Shoulder Bleeding disorders Anticoagulant medication Aspirin intake during the last 3 days Other pathologies of the shoulder such as tendonitis, and impingement

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

After initial assessments, patients are randomly assigned to one of the two groups of intervention 1 and intervention 2 (method: simple randomization - unit: individual). One envelope containing blue paper and one envelope containing red paper (randomization tool: sealed envelope) are given to the patients, if the patient choose the envelope containing blue paper, will be in the intervention group 1 and if he chose the envelope containing red paper will be in the intervention group 2.

Blinding (investigator's opinion)

Double blinded

Blinding description

As mentioned above, the study will be double-blinded. In this way, the participants do not know in which group they are. Participants only know that shockwave are used for them and have no knowledge of the type of probe (focused, radial). The data analyzer is also unaware of which study group the data belongs to. But the therapist, who is the one applying the different probes, assessing the outcome measures, knows the

participants' groups

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

Vice Chancellor for Research, 6th Floor, Central University Organization, Corner of Ghods St, Keshavarz Blvd

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Province

Tehran

Postal code

1417653761

Approval date

2022-03-06, 1400/12/15

Ethics committee reference number

IR.TUMS.FNM.REC.1400.216

Health conditions studied**1****Description of health condition studied**

Adhesive Capsulitis of Shoulder

ICD-10 code

M75.0

ICD-10 code description

Adhesive capsulitis of shoulder

Primary outcomes**1****Description**

Pain at rest

Timepoint

Before intervention- After the last session of intervention

Method of measurement

Visual Analogue Scale

2**Description**

Pain during activity

Timepoint

Before intervention- After the last session of intervention

Method of measurement

Visual Analogue Scale

3**Description**

Range of Motion

Timepoint

Before intervention- After the last session of intervention

Method of measurement

Goniometer

4**Description**

Function

Timepoint

Before intervention- After the last session of intervention

Method of measurement

The DASH (Disabilities of the Arm, Shoulder, and Hand) scale

5**Description**

Scapular Dyskinesia

Timepoint

Before intervention- After the last session of intervention

Method of measurement

Caliper

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: Group 1 (n = 20) will receive extracorporeal shockwave radial probe with conventional therapy (Infra-red, Ultrasound, supervised exercise & home exercises, two sessions in a week for four weeks.

Category

Rehabilitation

2**Description**

Intervention group 2: Group 2 (n = 20) will receive extracorporeal shockwave focused probe with conventional therapy (Infra-red, Ultrasound, supervised exercise & home exercises, two sessions in a week for four weeks.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tehran University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Sara Fereydounnia

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals.

When the data will become available and for how long

Access period starts 3 months after the articles are published.

To whom data/document is available

For researchers working in academic, scientific and hospital institutions

Under which criteria data/document could be used

Researchers working in the field of musculoskeletal physiotherapy and electrotherapy.

From where data/document is obtainable

Applicants for documentation can contact Dr. Sara Fereydounnia via email. S-fereydounnia@sina.tums.ac.ir

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

Once they have the necessary criteria, the information will be provided to them within a month.

Comments