

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7752 8468

##### Email address

s-fereydounnia@sina.tums.ac.ir

##### 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

**City**

Tehran

**Province**

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**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**

Sara Fereydounnia

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

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**Full name of responsible person**

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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**

Physiotherapy

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## Person responsible for scientific inquiries

### Contact

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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**

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**