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)

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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

City
Tehran

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
Sara Fereydounnia
Street address
Vice Chancellor for Research and Technology, sixth floor, Central University Organization, corner of Quds Street, Keshavarz Boulevard
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Sponsors / Funding sources

1

Sponsor
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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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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