Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation the effect of TECAR and exercise therapy protocol on pain reduction and functional improvement of in patients with frozen shoulder

Protocol summary

Study aim
Evaluation the effect of TECAR and exercise therapy protocol on pain reduction and functional improvement of in patients with frozen shoulder

Design
Randomised control trial with two group, intervention and control, single blinded, pre and post operative care

Settings and conduct
Tarbiat Modares University Motion analysis laboratory Prossessor blinded

Participants/Inclusion and exclusion criteria
inclusion criteria: patients in age 40-65 years. 3-6 months have passed since the onset of symptoms (Frozen phase). The onset of pain is not traumatic or secondary and the disease is primary. Pain during flexion or abduction is in the range of 3-5 VAS. At least 30% limitation of motion compared to the healthy side in flexion, abduction, and rotation (internal and external) movements, both active and passive (neither the patient nor the examiner is able to complete the range of motion).MRI should be negative and without associated pathology. Hawkins and Jobs clinical tests should be negative Exclusion criteria: Physiotherapy treatment in the past three months Change in medication regimen in the past three months History of pathologies such as cervical and thoracic involvement, rotator cuff injury, arthritis, history of trauma, fracture and surgery in the shoulder of the healthy and affected side.Local steroid injection or any intra-articular injection of the shoulder within the past six months Shoulder muscle strength less than 3 on MMT Exclusion criteria: Unwillingness to continue cooperation Emergence of any unforeseen problem

Intervention groups
TECAR and exercise therapy group Sham and exercise group

Main outcome variables
pain function tissue elasticity characteristic changes

General information

Reason for update
changing the supervisor and one of the assessment methods

Acronym

IRCT registration information
IRCT registration number: **IRCT20220305054195N1**
Registration date: **2022-11-21, 1401/08/30**
Registration timing: **prospective**

Last update: **2025-11-06, 1404/08/15**
Update count: **1**

Registration date
2022-11-21, 1401/08/30

Registrant information

Name
Fateme Babaei Heris

Name of organization / entity
Tarbiat Modares University

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-11-21, 1404/08/30

Expected recruitment end date
2026-04-20, 1405/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation the effect of TECAR and exercise therapy protocol on pain reduction and functional improvement of in patients with frozen shoulder

Public title
Investigation of the effect of tecar and exercise therapy on pain and function of frozen shoulder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People between the ages of 40 and 65 3-6 months have passed since the onset of symptoms (Frozen phase) The onset of the pain is not traumatic or secondary and the disease is primary. Pain during flexion or abduction should be in the range of 3-5 VAS. There should be a limitation of movement of at least 30% compared to the healthy side in flexion, abduction, and rotation (internal and external) movements, both active and passive (neither the patient nor the examiner is able to complete the range of motion). MRI should be negative and without associated pathology. Hawkins and Jobs' clinical tests are negative.

Exclusion criteria:
Physiotherapy treatment in the past 3 months Changes in medication regimen in the past three months History of pathologies such as cervical and thoracic involvement, rotator cuff injury, arthritis, history of trauma, fracture, and surgery in the shoulder of the healthy and affected side Local steroid injection or any injection into the shoulder joint within the past six months قدرت عضلات شانه کمتر از 3 در MMT

Age
From **45 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data and Safety Monitoring Board

Sample size
Target sample size: **12**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to implement a random sequence on participants, in a way that is not specified before the individual assignment, the assigned group is used to Sequentially numbered, sealed, opaque envelopes (SNOSE) .At the start of the enterance of participants, based on the arrangement of eligible participants to study, one of the letter envelopes is opened. Based on sample size, a number of papers are prepared and each random sequence created on a record card inside the envelopes. In order to maintain a random sequence, the number of papers is made in the same order and placed inside the box. At the time of the start of the participants' registration, based on the arrival of the study, one of the envelopes is opened and the allocated group of this participant is revealed.

Blinding (investigator's opinion)
Single blinded

Blinding description
the data proccessor doesnt know about every person belong to which group therefore she would compare and judge the datas whithout bias.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of tarbiat modares university

Street address
Jalal_e_ale_ahmad

City
Tehran

Province
Tehran

Postal code
1411713116

Approval date
2022-10-31, 1401/08/09

Ethics committee reference number
IR.MODARES.REC.1401.157

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
pain score

Timepoint
Before and 48 hours after the intervention

Method of measurement
shoulder pain and disability scale (SPADI) Questionnaire

2

Description
tendon elasticity
Timepoint
Before and 48 hours after the intervention
Method of measurement
sonography

3

Description
Shoulder joint kinetics
Timepoint
Before and 48 hours after the intervention
Method of measurement
vicon system motion analysis

4

Description
Disability score
Timepoint
Before and 48 hours after the intervention
Method of measurement
shoulder pain and disability scale (SPADI) Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: TECAR therapy, 7 sessions for every patient, 3 days per week, every session 20 minuts duration, with coupling medium cream as intermediator 20 milimeter for every one.
Category
Treatment - Devices

2

Description
Control group: sham group and intensity is zero
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Motion analysis laboratory of Tarbiat modares univercity
Full name of responsible person
Fateme Babaei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tarbiat Modares Univercity
Full name of responsible person
Dr Roya Ravanbod
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med@modares.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tarbiat Modares Univercity
Proportion provided by this source
80
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
Tarbiat Modares Univercity
Full name of responsible person
Fateme Babaei
Position
Ph.D Candidate
Latest degree
Master
Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be 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
Providing data after analysis and conclusions

When the data will become available and for how long
Providing data after analysis and conclusions

To whom data/document is available
supervisor

Under which criteria data/document could be used
to using other researchers

From where data/document is obtainable
researcher

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

Comments