Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Study and comparison of the course of frozen shoulder after intra-articular steroid injection versus patients treated with TECAR therapy in Shahrekord city : A randomized clinical trial

Protocol summary

Study aim

Determination and comparison of shoulder joint range of motion (internal rotation, external rotation, anterior flexion) in the study groups across the assessed time points Assisting in the selection of the optimal treatment method for patients with frozen shoulder in physiotherapy and pain management clinics Providing scientific evidence to improve rehabilitation and treatment protocols for patients with frozen shoulder in Iran Reducing patient treatment costs by selecting more effective treatment methods and shortening the period of disability

Design

A two-phase, single-blind, parallel-group, controlled clinical trial involving 44 patients, with randomization performed using randomization software.

Settings and conduct

This study was designed as a single-blind, randomized clinical trial in Shahrekord to investigate the effect of intraarticular steroid injection compared to TECAR therapy on the recovery of patients with frozen shoulder.To minimize observer bias, each patient will be assigned a unique code by the treating physician, and patients will be identified by these codes.

Participants/Inclusion and exclusion criteria

Diagnosis of frozen shoulder Age 40–60 years Willingness and informed consent to participate in the study Absence of radiculopathy Absence of osteoarthritis Absence of severe diabetes No prior treatment in the shoulder area

Intervention groups

The first group will undergo treatment with an intraarticular steroid injection. Triamcinolone acetonide (40 mg) will be used in this study. The second group will undergo TECAR therapy. Treatment will consist of five sessions, each lasting approximately 15 minutes, administered over a two-week period.

Main outcome variables

Assisting in the selection of the optimal treatment method for patients with frozen shoulder, and reducing treatment costs by choosing a more effective approach and shortening the period of disability.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260906070929N2**
Registration date: **2026-10-14, 1405/07/22**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-14, 1405/07/22**
Update count: **0**

Registration date

2026-10-14, 1405/07/22

Registrant information

Name

Ashkan Salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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salehi.ashkan@skums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-13, 1405/07/21

Expected recruitment end date

2027-04-20, 1406/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study and comparison of the course of frozen shoulder after intra-articular steroid injection versus patients treated with TECAR therapy in Shahrekord city : A randomized clinical trial

Public title

Comparison of the Effects of Steroid Injection and TECAR Therapy on Frozen Shoulder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Developing frozen shoulder Ages 40 to 60 Willingness and informed consent to participate in the research Absence of radiculopathy Absence of osteoarthritis Absence of severe diabetes No prior treatment in the shoulder area

Exclusion criteria:

prior treatment in the shoulder area Developing severe diabetes Developing osteoarthritis Developing radiculopathy

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization Randomization unit: Individual Measurement tool: Random selection software Eligible participants who meet the inclusion criteria will be informed about the study, and written informed consent will be obtained before enrollment. Participants will then be randomly assigned to one of two intervention groups: the intra-articular corticosteroid injection group or the TECAR therapy group. Random allocation will be performed using Random Allocation Software. The study will include 44 participants, with a target of 22 participants in each group. To maintain balanced group sizes throughout recruitment, block randomization may be used to generate the allocation sequence. The allocation sequence will be prepared by an independent individual who is not involved in participant recruitment, treatment administration, or outcome assessment. Allocation concealment will be maintained until each participant has been enrolled and is ready to receive the assigned intervention, using sequentially numbered, opaque, sealed envelopes. All interventions will be performed by a specialist in Physical Medicine and Rehabilitation. Due to the nature of the interventions, blinding of participants and the treating specialist will not be feasible. However, outcome assessments will be conducted by an orthopedist and a medical student who will remain unaware of the participants' group assignments. Participants' demographic and clinical data, treatment allocation, and outcome measurements will be recorded using study identification codes to maintain confidentiality.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is designed as a single-blind trial. Following the random assignment of patients to two treatment groups, all interventions—including intra-articular steroid injections and TECAR therapy—will be performed by a specialist in physical medicine and rehabilitation. Given the distinct nature of the two treatment modalities, blinding both the patient and the administering physician is not feasible; consequently, both the patients and the treating physician will be aware of the assigned treatment. To minimize assessment bias, the treating physician will assign a specific code to each patient, and patients will be identified solely by these codes. All clinical assessments at the scheduled time points will be conducted by an orthopedist and a student—who will remain unaware of the patients' identities and the specific interventions administered—based exclusively on the patient codes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine - Shahrekord University Of Medical Sciences

Street address

Ayatollah Kashani Hospital, Parastar St., Shahrekord, Chaharmahal and Bakhtiari Province

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Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

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Approval date

2026-09-23, 1405/07/01

Ethics committee reference number

IR.SKUMS.MED.REC.1405.160

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
Total score of the Shoulder Pain and Disability Index questionnaire
Timepoint
Measurement of the total score on the Shoulder Pain and Disability Index (SPADI) questionnaire at baseline and at 1 and 3 months after the start of treatment.
Method of measurement
Pain and Disability Index (SPADI) questionnaire

Secondary outcomes

1

Description
Visual Analogue Scale (VAS) questionnaire score
Timepoint
At baseline, and 1 month and 3 months after the start of treatment
Method of measurement
Visual analogue scale

Intervention groups

1

Description
Intervention group: They will undergo intraarticular steroid injection. The injection will be performed under ultrasound guidance by a single practitioner (a physical medicine specialist). The medication used will be triamcinolone acetonide (40 mg/mL); a volume of 1 mL will be injected, combined with 2 mL of 1% lidocaine, in a single session. Following the injection, patients will receive instructions regarding relative rest and the performance of gentle pendulum exercises for the shoulder. No other physiotherapy or pharmacological treatment will be prescribed during the follow-up period, so that the isolated effect of the injection can be evaluated.
Category
Treatment - Drugs

2

Description
Intervention group: Patients will undergo Tecar therapy. The treatment will consist of five sessions—each lasting approximately 15 minutes—conducted over a two-week period. The therapy will be administered using a device featuring both capacitive and resistive modes: the capacitive mode will target superficial tissues such as muscles, while the resistive mode will address deeper tissues, including tendons and joint capsules. An experienced physiatrist will perform the treatment, adjusting the current intensity according to the patient's tolerance threshold to ensure a pleasant warming sensation without any burning. Patients will be positioned comfortably and correctly throughout the procedure, and no supplementary medications or injections will be used.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Specialized and Subspecialized Clinic, Shahrekord
Full name of responsible person
Ashkan Salehi
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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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res.med@skums.ac.ir
Web page address
https://medresearch.skums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
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Ashkan Salehi
Position
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Latest degree
Specialist
Other areas of specialty/work
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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

Undecided - It is not yet known if there will be 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