Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Effect of Oral Mucosa Stem Cell Therapy and Standard Surgical Repair on Pain Relief, Healing, and Shoulder Function in Patients with Rotator Cuff Muscle Tear: A Randomized Clinical Trial

Protocol summary

Study aim

The aim of this study is to evaluate the effect of oral mucosa stem cells compared with standard surgical repair on pain relief, tissue healing, and shoulder function in patients with rotator cuff muscle tear.

Design

Randomized, double-blind, parallel-group, phase 2 clinical trial on 20 patients; randomization was performed using a random number table generated in SPSS, with allocation concealed in sealed opaque envelopes.

Settings and conduct

The study is conducted in the orthopedic department and operating room of Shahid Bahonar Hospital, Kerman. Stem cell sampling is performed by an independent team, and injections are carried out by the same surgeon. Patients and outcome assessors are blinded to the type of treatment. Follow-up continues for three months after surgery.

Participants/Inclusion and exclusion criteria

Participants include patients over 18 years of age with full-thickness supraspinatus tendon tear and shoulder pain or weakness lasting more than three months; exclusion criteria include pregnancy, shoulder osteoarthritis, previous shoulder surgery or fracture, rheumatic diseases, chronic corticosteroid use, coagulation disorders, and severe uncontrolled comorbid diseases.

Intervention groups

The intervention group receives oral mucosa stem cell therapy combined with standard surgical repair; the control group receives standard surgical repair without stem cell injection.

Main outcome variables

Shoulder pain intensity based on Visual Analogue Scale (VAS); shoulder range of motion; shoulder function using Constant score; tendon healing on follow-up MRI.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250823066963N2**
Registration date: **2025-10-12, 1404/07/20**
Registration timing: **prospective**

Last update: **2025-10-12, 1404/07/20**
Update count: **0**

Registration date

2025-10-12, 1404/07/20

Registrant information

Name

Ali Torabi nejad kermani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-10-23, 1404/08/01

Expected recruitment end date

2028-03-19, 1406/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the Effect of Oral Mucosa Stem Cell Therapy and Standard Surgical Repair on Pain Relief, Healing, and Shoulder Function in Patients with Rotator Cuff Muscle Tear: A Randomized Clinical Trial

Public title
Effect of Oral Mucosa Stem Cells on Healing and Shoulder Function in Patients with Rotator Cuff Muscle Tear

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years Written informed consent to participate in the study Full-thickness tear of the supraspinatus tendon Retraction less than 30 mm on MRI No fatty degeneration in the rotator cuff muscle Shoulder pain or weakness for at least 3 months without improvement with non-surgical treatment

Exclusion criteria:
Pregnancy Shoulder osteoarthritis Previous shoulder surgery or fracture Psychiatric disorders or fibromyalgia Painful cervical spine pathology Rheumatic diseases Chronic corticosteroid or NSAID use Coagulation disorders or thrombocytopenia Vascular or neurological shoulder lesions Severe uncontrolled comorbid diseases

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, eligible patients were randomly assigned to either the intervention group (oral mucosa stem cell therapy combined with standard surgical repair) or the control group (standard surgical repair only) after initial assessment and obtaining written informed consent. Randomization was simple randomization, and the unit of randomization was individual. The random sequence was generated using a random number table in SPSS version 26 by an independent researcher who was not involved in the intervention or outcome assessment. To ensure allocation concealment, the randomization codes were sealed in opaque, sequentially numbered envelopes. Each envelope was opened only at the time of participant enrollment, ensuring that neither the surgeon nor the outcome assessor was aware of the allocation beforehand.

Blinding (investigator's opinion)
Double blinded

Blinding description
A double-blind design was applied in this trial. Participants were unaware of their group assignment (whether they received stem cell injection or not). All patients underwent the same surgical procedure with identical incisions to prevent awareness of treatment differences. Stem cell sampling and preparation of the suspension were performed by an independent laboratory team, separate from the surgical staff. The injection (stem cell suspension or normal saline) was administered by the same surgeon, who was blinded to the content of each coded syringe prepared by the independent team. Nurses and physiotherapists responsible for postoperative care were not informed about group allocation. The evaluator of shoulder function and the data analyst were also blinded to the intervention type to minimize measurement and interpretation bias. Randomization codes were opened only after completion of data collection by the principal investigator.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kerman University of Medical Sciences

Street address
Beginning of Haft Bagh Alavi Blvd., Kerman University of Medical Sciences Campus

City
Kerman

Province
Kerman

Postal code
7616913555

Approval date
2025-08-12, 1404/05/21

Ethics committee reference number
IR.KMU.AH.REC.1404.097

Health conditions studied

1

Description of health condition studied
Rotator cuff tear of shoulder

ICD-10 code
M75.1

ICD-10 code description
Rotator cuff tear or rupture, not specified as traumatic

Primary outcomes

1

Description
Shoulder pain intensity based on the Visual Analogue Scale
Timepoint
At baseline (before intervention) and at one, two, and three months after surgery
Method of measurement
Pain intensity is measured using a ten-centimeter Visual Analogue Scale where zero indicates no pain and ten indicates the worst imaginable pain

2

Description
Shoulder joint range of motion in flexion, extension, abduction, and external rotation
Timepoint
At baseline and three months after surgery
Method of measurement
Range of motion is measured using a goniometer by a trained physiotherapist in standardized positions

3

Description
Tendon healing status in follow-up imaging
Timepoint
Three months after surgery
Method of measurement
Tendon healing is evaluated using magnetic resonance imaging (MRI) interpreted by an independent radiologist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in this group receive oral mucosa–derived mesenchymal stem cell therapy combined with standard surgical repair of the rotator cuff tendon.Initially, a small biopsy (approximately 3×3 millimeters) is obtained from the oral mucosa under local anesthesia. Mesenchymal stem cells are isolated and expanded in a specific culture medium under sterile conditions. During surgical repair, a cell suspension containing approximately one million cells in one milliliter of normal saline is injected at the tendon–bone interface. This procedure is performed during the same surgical session. After surgery, patients are followed according to the standard rehabilitation protocol.
Category
Treatment - Surgery

2

Description
Control group:Patients in this group undergo standard surgical repair of the rotator cuff tendon without any stem cell or additional injection.The surgical procedure involves open or arthroscopic repair of the torn tendon using nonabsorbable sutures at the tendon–bone junction. All surgeries are performed by the same surgeon, and postoperative care and rehabilitation protocols are identical in both groups.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Bahonar Hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Kerman 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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Full name of responsible person
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Position
Orthopedic resident
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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