

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The evaluation of effectiveness of mesenchymal stem cell derived from autologous adipose tissue compared to platelet rich plasma on pain and functionality of the patients with total tear of shoulder rotator cuff tendons (The second phase of a clinical trial)

Protocol summary

Study aim

To determine the effectiveness of mesenchymal stem cell compared to platelet rich plasma on pain and functionality of the patients with total tear of shoulder rotator cuff tendons

Design

the second phase of a randomized single blinded clinical trial on 30 patients in two groups, PRP and stem cells are compared with each other

Settings and conduct

Patients with full rotator cuff tear who visit Rasoul Akram hospital divide in two groups by block randomization, platelet rich plasma and mesenchymal stem cell treatment. patients evaluate for shoulder range of motion, muscle strength, pain level, daily activity performance, tendon tear size on MRI before intervention, one, three and six months after intervention. Study is single blinded to data analyzer

Participants/Inclusion and exclusion criteria

Inclusion criteria: Chronic shoulder pain (lasting over three months) Confirmed complete tear of the tendons on shoulder MRI; At least positive five clinical shoulder tests including Neer, Hawkins, Jobe, extension lag, drop arm, resisted external and internal rotation; Age over 30 years; lack of patient consent for tendon surgery
exclusion criteria: Active malignancy or history of malignancy in the last 5 years in any area of the body; Calcific tendinitis; Adhesive capsulitis; History of receiving biological factor treatments in the past six months; Partial tears of the rotator cuff tendons; Emergency surgical indications

Intervention groups

One group received platelet rich plasma and other group received mesenchymal stem cell derived from autologous adipose tissue

Main outcome variables

Pain; Tendon tear repair; Joint range of motion; ;
Functionality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100718004409N16**

Registration date: **2025-02-04, 1403/11/16**

Registration timing: **prospective**

Last update: **2025-02-04, 1403/11/16**

Update count: **0**

Registration date

2025-02-04, 1403/11/16

Registrant information

Name

Parisa Nejati

Name of organization / entity

Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-05, 1403/12/15

Expected recruitment end date

2026-03-06, 1404/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of effectiveness of mesenchymal stem cell derived from autologous adipose tissue compared to platelet rich plasma on pain and functionality of the patients with total tear of shoulder rotator cuff tendons (The second phase of a clinical trial)

Public title

Mesenchymal stem cell in rotator cuff tear

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chronic shoulder pain (lasting over three months)
Confirmed complete tear of at least on tendon in shoulder MRI At least positive five clinical shoulder tests including Neer, Hawkins, Jobe, extension lag, drop arm, resisted external and internal rotation Age over 30 years

Exclusion criteria:

Active malignancy or history of malignancy in the last 5 years in any area of the body Calcific tendinitis Adhesive capsulitis History of receiving biological factor treatments in the past six months Partial tears of the rotator cuff tendons Emergency surgical indications

Age

From 30 years old

Gender

Both

Phase

2

Groups that have been masked

- Data analyser

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is base on block randomization. The 30 participants divided in five blocks, each includes six. Three patients will take PRP and three patients will take stem cells in each group. The allocation of each one in each block is based on opening the envelops that determine type of intervention.

Blinding (investigator's opinion)

Single blinded

Blinding description

Analyzer of the data is blinded to the intervention groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Iran university of medical sciences

Street address

Iran University of Medical Sciences, Near the Milad Tower, Hemmat Highway

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1449614535

Approval date

2024-12-22, 1403/10/02

Ethics committee reference number

IR.IUMS.FMD.REC.1403.424

Health conditions studied

1

Description of health condition studied

Full tear of shoulder rotator cuff tendon

ICD-10 code

M75.1

ICD-10 code description

Rotator cuff tear or rupture, not specified as traumatic

Primary outcomes

1

Description

Pain

Timepoint

Before intervention and 1, 3, 6 months after injection

Method of measurement

Visual Analogue Scale Score

2

Description

Tendon tear repair

Timepoint

Before intervention, 6 months after injection

Method of measurement

Magnetic Resonance Imaging

Secondary outcomes

1

Description

Joint range of motion

Timepoint

Before intervention and 1, 3, 6 months after injection

Method of measurement

Hand held goniometry

2

Description

Muscle strength

Timepoint

Before intervention and 1, 3, 6 months after injection

Method of measurement

Muscle strength testing scale on 1-5

3

Description

Functionality

Timepoint

Before intervention and 1, 3, 6 months after injection

Method of measurement

Western Ontario Rotator Cuff and Disabilities of the Arm, Shoulder and Hand

Intervention groups

1

Description

Intervention group: First, 20 to 30 cc of fat is collected via liposuction in sterile conditions from the abdomen and flank areas of the patient and sent to the hospital's Motahari Clean Room laboratory for preparation. Flow cytometry tests are performed, and CD markers are checked. After the mesenchymal cells are prepared (2 to 3 months after the process begins), the sample will be sent to the sports medicine department of Rasoul Akram Hospital. At the same time, 1 cc of the solution containing the prepared cells will be injected into the torn tendon under ultrasound guidance.

Category

Treatment - Other

2

Description

Control group: For preparing Platelet Rich Plasma, 35 cc of venous blood will be drawn from the patients and placed in a centrifuge. The separated plasma from the first centrifugation for 10 minutes at 1600 Revolutions Per Minute (RPM) will be drawn in the tubes, and the second centrifugation will last for 6 minutes at 3200 RPM. Then, 3 cc from the end of each tube, after removing the upper plasma, will be drawn into a syringe. The injection will be performed under ultrasound guidance into the tear tendon.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran university of medical sciences, Rasool hospital, sports medicine clinic

Full name of responsible person

Parisa Nejati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Safa Majid

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Parisa Nejati

Position

Associate Professor of Sports Medicine/specialist

Latest degree

Specialist

Other areas of specialty/work

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Tehran

Province

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Postal code

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The plan will be design after starting the study

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available