Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
Iran (Islamic Republic of)

Phone
+98 21 4480 0361

Email address
parisanejati@iums.ac.ir

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
City
Tehran
Province
Tehran
Postal code
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
Street address
Sattarkhan, Niayesh st.
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 6435 2446
Email
parisanejati2@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Safa Majid
Street address
Shahid Hemmat Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 86701
Email
info@iums.ac.ir
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
Sport Medicine
Street address
Sports Medicine Department , 8 th floor , Rasoul Akram Hospital , Niayesh Street , Satarkhan Street , Tehran
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6435 2446
Fax
Email
Parisanejati@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Parisa Nejati
Position
Sports medicine specialist, Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Sport Medicine
Street address
Sports medicine department, Rasoul Akram hospital, Niayesh Avenue, Satarkhan street,
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6435 2446
Fax
Email
parisanejati@yahoo.com
Web page address

Person responsible for updating data

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
Sport Medicine
Street address
Sports Medicine Department , 8 th floor , Rasoul Akram Hospital , Niayesh Street , Satarkhan Street , Tehran
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6435 2446
Email
Parisanejati@yahoo.com

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