

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Comparison of Ultrasound-Guided Local Corticosteroid Injection versus Mesenchymal Stem Cell Origin of Adipocytes ( Allogeneic ) in patient with Rotator Cuff Tendinopathy

#### Protocol summary

##### Study aim

Comparison of the effect of ultrasound-guided corticosteroid injections with allogeneic mesenchymal stem cell in patients with rotator cuff tendonitis in the shoulder

##### Design

Subacromial injection of 1 cc equivalent of forty mg triamcinolone with 1 cc lidocaine is performed in a bursa near the parietal rupture, gage 22 and ultrasound guidance. In the other group allogeneic mesenchymal stem cells are injected 30 × 10<sup>6</sup> mesenchymal stem cells are injected 1 cc with 1 cc lidocaine in sterile conditions in the area with partial rupture.

##### Settings and conduct

Patients with shoulder tendonopathy are selected from referrals to physical medicine clinics of Iran University of Medical Sciences. Patients were randomly divided into two groups, each with a closed envelope method.

##### Participants/Inclusion and exclusion criteria

Main Inclusion Criteria: Tendinopathy in patients with positive shoulder specific tests including: Neer test, Hawkins test VAS more than 4; no history of poor control of diabetes, coagulopathy, fractures, rheumatologic diseases, tumors and systemic infections , Not having shoulder injection in last 4 months. Main Exclusion Criteria: Patients who cannot be referred for follow-up by any other means, complete rotator cuff rupture, possibility of cervical radiculopathy, myofascial trigger point

##### Intervention groups

Intervention group: Allogeneic Stem Cell Injection in the area with partial rupture with Ultrasound-guided Lateral Approach. Control group: Ultrasound-guided injection of corticosteroid in the subacromial space with the lateral approach.

##### Main outcome variables

The severity of symptoms by Visual Analog Scale (VAS) ,

Shoulder Disability by Quick Disabilities of Arm, Shoulder & Hand (Quick DASH)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151017024572N21**

Registration date: **2020-01-09, 1398/10/19**

Registration timing: **prospective**

Last update: **2020-01-09, 1398/10/19**

Update count: **0**

##### Registration date

2020-01-09, 1398/10/19

##### Registrant information

##### Name

Arash Babaei-Ghazani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8895 8991

##### Email address

babaei-ghazani.a@iums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2020-01-21, 1398/11/01

##### Expected recruitment end date

2021-08-23, 1400/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of Ultrasound-Guided Local Corticosteroid Injection versus Mesenchymal Stem Cell Origin of Adipocytes ( Allogeneic ) in patient with Rotator Cuff Tendinopathy

**Public title**  
Effect of Mesenchymal Stem Cell in Rotator Cuff Tendinopathy

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
The presence of tendinopathy in patients with positive shoulder specific tests including: Neer test, Hawkins test Visual Analogue Scale more than 4 Lack of history of poor control Diabetes, coagulopathy, fractures, rheumatologic diseases, tumors and systemic disease infection No history of shoulder injections in the last 4 months Patient's age 18 to 65 years No pregnancy or decision to become pregnant Lack of risk factor for intra articular injection such as coagulation disorders or Use of anticoagulants Lack of mental disorder Patient willingness to participate in research project  
**Exclusion criteria:**  
Patients who have not been followed for any reason Changes in the patient's treatment according to the physician or Other treatment by the patient during the study History of shoulder surgery Complete rotator cuff rupture History of cervical radiculopathy Myofascial trigger points

**Age**  
From **18 years** old to **65 years** old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**  
Target sample size: **30**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Method of randomization: block, Unit of randomization: individual, Tools used in randomization: table of random numbers

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
This is a double-blind study in which patients and outcomes analyzer are blinded. In order to blind the patient, it is said that both materials are effective for treatment, but the type of substance is not mentioned for patients when its injected. In order to blind the

analyzer, the persons responsible for injection and data collection are different from the outcome assessors.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
Block randomization

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Iran University of Medical Science

##### Street address

Medical faculty, Iran University of Medical Science, Hemmat High way

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

#### Approval date

2019-04-07, 1398/01/18

#### Ethics committee reference number

IR.IUMS.REC.1398.081

## Health conditions studied

### 1

#### Description of health condition studied

Shoulder tendinopathy

#### ICD-10 code

M75.4

#### ICD-10 code description

Impingement syndrome of shoulder

## Primary outcomes

### 1

#### Description

The severity of symptoms

#### Timepoint

Zero, two weeks , three months , six months later (Since the injection)

#### Method of measurement

Visual Analog Scale (VAS)

### 2

#### Description

Shoulder Pain and Disability

#### Timepoint

Zero, two weeks , three months , six months later (Since the injection)

**Method of measurement**

Quick Disabilities of Arm, Shoulder & Hand (Quick DASH)

## Secondary outcomes

### 1

**Description**

Side effects

**Timepoint**

30 minutes and tow weeks (Since the injection)

**Method of measurement**

Physical examination

## Intervention groups

### 1

**Description**

Intervention group: Allogeneic Stem Cell Injection in the area with partial rupture with Ultrasound-guided Lateral Approach

**Category**

Treatment - Other

### 2

**Description**

Control group: Ultrasound-guided injection of corticosteroid in the subacromial space with the lateral approach.

**Category**

Treatment - Other

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Firoozgar Hospital

**Full name of responsible person**

Nariman samadaeian

**Street address**

Department of Physical Medicine and Rehabilitation,  
Firuzgar Hospital, Valiasr Square

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Nariman.samadaeian@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Seyed Kazem Malakooti

**Street address**

5th floor, Headquarters, Iran University of Medical  
Sciences, Hemmat Highway, Tehran

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PR@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**

Nariman samadaeian

**Position**

Resident of Physical Medicine and Rehabilitation

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

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## Person responsible for scientific inquiries

**Contact**

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Dr. Arash Babaei

**Position**

Associate Professor of Physical Medicine and Rehabilitation

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

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## 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**

There is no further information.

**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