

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Comparative study of the effectiveness of intra-articular injection of methylprednisolone at doses of 20 and 40 mg in patients aged 20 to 60 years with mild rotator cuff injury

#### Protocol summary

##### Study aim

Comparative study of the effectiveness of intra-articular injection of methylprednisolone with two doses of 20 and 40 mg in patients aged 20 to 60 years with mild rotator cuff injury

##### Design

This study is a randomized clinical trial with a parallel design, a single-blinded with a control group. This study is randomized, phase 2-3 study will be performed on 57 eligible patients. Random blocking is used for randomization and participants are assigned to two intervention groups and a control group.

##### Settings and conduct

This study, which will be conducted in Taleghani Hospital of Kermanshah, is a single-blinded one and the statistical analyst will be kept blind. Researchers and participants have no role in the process of randomization and assignment of intervention and control groups.

##### Participants/Inclusion and exclusion criteria

Include criteria: Patients aged 20 to 60 years; Detection of rotator cuff rupture to the extent of tendinosis.  
Exclude criteria: Patients with more severe tears than tendinosis; history of fractures; Frozen shoulder; History of previous shoulder injections; Patients treated with oral or systemic injectable steroids; Concurrent lipoma or DJD joint injuries or concomitant shoulder instabilities

##### Intervention groups

In the first intervention group, patients will receive 40 mg of methylprednisolone by intra-articular injection. In the second intervention group, patients will receive 40 mg of methylprednisolone by intra-articular injection. In the control group, the same infrared physiotherapy will be performed with a wavelength of 1000 angstroms.

##### Main outcome variables

Shoulder function; Pain intensity; Shoulder function limitations

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130812014333N187**

Registration date: **2022-06-19, 1401/03/29**

Registration timing: **prospective**

Last update: **2022-06-19, 1401/03/29**

Update count: **0**

##### Registration date

2022-06-19, 1401/03/29

##### Registrant information

##### Name

Feizollah Foroughi

##### Name of organization / entity

kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1821 4653

##### Email address

froughi@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-06, 1401/04/15

##### Expected recruitment end date

2022-10-07, 1401/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparative study of the effectiveness of intra-articular injection of methylprednisolone at doses of 20 and 40 mg in patients aged 20 to 60 years with mild rotator cuff injury

### Public title

Comparative study of the effectiveness of intra-articular injection of methylprednisolone at doses of 20 and 40 mg in patients with mild shoulder injury

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients aged 20 to 60 years Detection of rotator cuff rupture to the extent of tendinosis

#### Exclusion criteria:

Patients with more severe tears than tendinosis; history of fractures Frozen shoulder History of surgery History of previous shoulder injections Patients treated with oral or systemic injectable steroids Concurrent lipoma or DJD joint injuries or concomitant shoulder instabilities

### Age

From **20 years** old to **60 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

- Data analyser

### Sample size

Target sample size: **57**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Randomization using the blocking method with blocks in sizes 6 and 9. For randomization, the site <https://www.sealedenvelope.com> is used. All codes are recorded on paper and stored in specific envelopes. Each of the generated codes is kept separately inside the envelope and the secretary gives one of these envelopes to the patient before the patient enters the doctor's room. Accordingly, the next patient code is not predictable. The doctor determines which treatments to perform based on the patient's code. Only the physician performing the intervention will be aware of the code assigned to the patient. After evaluating the outcome, based on the patient's name, the collected information will be linked to the assigned code.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

In this study, the statistical analyst will be kept blind. The code of the groups in the statistical and analysis software is not known to the analyst and only the main researcher is aware of it. Patients will also be aware of their treatment.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

##### Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

#### Approval date

2022-03-13, 1400/12/22

#### Ethics committee reference number

IR.KUMS.MED.REC.1401.030

## Health conditions studied

### 1

#### Description of health condition studied

rotator cuff tendinitis

#### ICD-10 code

S46.00

#### ICD-10 code description

Unspecified injury of muscle(s) and tendon(s) of the rotator cuff of shoulder

## Primary outcomes

### 1

#### Description

Shoulder function

#### Timepoint

The beginning of the study, the third, sixth and twelfth weeks

#### Method of measurement

Using the UCLA shoulder rating scale

### 2

#### Description

Intensity of pain

#### Timepoint

The beginning of the study, the third, sixth and twelfth weeks

**Method of measurement**

Using visual pain scale (VAS)

**3****Description**

Shoulder function limitations

**Timepoint**

The beginning of the study, the third, sixth and twelfth weeks

**Method of measurement**

Simple shoulder test

**Secondary outcomes**

empty

**Intervention groups****1****Description**

In the first intervention group, patients will receive 40 mg of methylprednisolone by intra-articular injection.

**Category**

Treatment - Drugs

**2****Description**

In the second intervention group, patients will receive 40 mg of methylprednisolone by intra-articular injection.

**Category**

Treatment - Drugs

**3****Description**

In the control group, the same infrared physiotherapy will be performed with a wavelength of 1000 angstroms

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Taleghani Hospital

**Full name of responsible person**

Mohammad Mahdi Rajabi

**Street address**

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847167

**Phone**

+98 83 3836 7984

**Email**

Mahdirajabi1899@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Cyrus Jalili

**Street address**

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3836 0014

**Email**

cjalili@kums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Mohammad Mahdi Rajabi

**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

Shahid Beheshti Boulevard, Taleghani Hospital

**City**

Kermanshah  
**Province**  
Kermanshah  
**Postal code**  
6715847167  
**Phone**  
+98 83 3836 7984  
**Email**  
Mahdirajabi1899@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Dr. Maziar Malekzadeh  
**Position**  
Faculty member of Kermanshah University of Medical Sciences  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Orthopedics  
**Street address**  
Shahid Beheshti Boulevard, Taleghani Hospital  
**City**  
Kermanshah  
**Province**  
Kermanshah  
**Postal code**  
6715847167  
**Phone**  
+98 83 3836 7984  
**Email**  
maziar.malekzadeh@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Mohammad Mahdi Rajabi  
**Position**  
medical student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
General Practitioner  
**Street address**  
Shahid Beheshti Boulevard, Taleghani Hospital  
**City**  
Kermanshah  
**Province**  
Kermanshah  
**Postal code**  
6715847167  
**Phone**  
+98 83 3836 7984  
**Email**  
Mahdirajabi1899@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

There is no more 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