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)

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

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
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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
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
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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Faculty member of Kermanshah University of Medical Sciences

Latest degree
Specialist

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Orthopedics

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Other areas of specialty/work
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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 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