

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Therapeutic efficacy of intramuscular methotrexate versus oral naproxen in adhesive capsulitis of the shoulder: a randomized controlled trial

Protocol summary

Study aim

To assess the effectiveness of methotrexate on adhesive capsulitis of the shoulder, in comparison to oral naproxen

Design

Pragmatic, Two-arm parallel randomized trial

Settings and conduct

The study is conducted as a randomized clinical trial. Random allocation is done using a random number table generated by Microsoft Excel. Intervention arms are oral naproxen vs. intramuscular methotrexate injection. Due to the difference in intervention, blinding is not applicable. Sampling will be done using the convenience method.

Participants/Inclusion and exclusion criteria

All patients diagnosed with primary adhesive capsulitis of the shoulder, older than 18 years old, without a history of trauma, or any secondary cause. Pregnant women, as well as patients with renal or hepatic insufficiency, are excluded.

Intervention groups

First: Intramuscular methotrexate; Second: Oral naproxen

Main outcome variables

Range of motion (ROM); Visual Analog Scale (VAS); Shoulder Pain and Disability Index Questionnaire (SPADI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181101041523N1**

Registration date: **2022-12-20, 1401/09/29**

Registration timing: **retrospective**

Last update: **2022-12-20, 1401/09/29**

Update count: **0**

Registration date

2022-12-20, 1401/09/29

Registrant information

Name

Sina Owlia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-30, 1397/11/10

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

2019-02-01, 1397/11/12

Actual recruitment end date

2020-03-05, 1398/12/15

Trial completion date

2020-03-05, 1398/12/15

Scientific title

Therapeutic efficacy of intramuscular methotrexate versus oral naproxen in adhesive capsulitis of the shoulder: a randomized controlled trial

Public title

Intramuscular methotrexate on adhesive capsulitis of the shoulder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients diagnosed with adhesive capsulitis older than 18 years old

Exclusion criteria:

History of trauma Evidence of degenerative processes
Active gastric ulcer History of GI bleeding History of
hepatitis Patients with renal insufficiency Pregnant
women

Age

From **18 days** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **31**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization would be done by allowing the included patients to choose among sealed and opaque envelopes containing the allocation to either of the treatment groups. As diabetes condition is strongly correlated with the disease (presumably 70% of patients with adhesive capsulitis), this parameter has been selected as the factor for stratified randomization. Patients with diabetes condition would choose from 'Diabetes strata' while patients without diabetes condition would choose an envelope from 'Non-Diabetes' strata.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahid Sadoughi University of Medical Sciences,
Ethics Committee

Street address

School of Medicine, Alem sq., Safaiyeh, Yazd, Iran

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Yazd

Province

Yazd

Postal code

۸۹۱۵۱۳۱۴۳

Approval date

2020-02-23, 1398/12/04

Ethics committee reference number

IR.SSU.MEDICINE.REC.1398.111

Health conditions studied**1****Description of health condition studied**

Adhesive capsulitis of the shoulder

ICD-10 code

M75.0

ICD-10 code description

Adhesive capsulitis of shoulder

Primary outcomes**1****Description**

Passive range of motion of the involved shoulder (flexion, abduction, internal rotation, external rotation)

Timepoint

Before intervention, and at 2, 4, and 8 weeks after intervention

Method of measurement

Analog Goniometer

2**Description**

Perceived pain

Timepoint

Before intervention, and at 2, 4, and 8 weeks after intervention

Method of measurement

Visual Analog Scale

3**Description**

Functional and disability outcomes

Timepoint

Before intervention, and at 2, 4, and 8 weeks after intervention

Method of measurement

Shoulder pain and disability index (SPADI) Questionnaire

Secondary outcomes

empty

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

Intervention group: Intramuscular methotrexate (12.5 mg every 10 days for 40 days)

Category

Treatment - Drugs

2**Description**

Intervention group: Oral Naproxen (500 mg Daily for 40

days)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Baghaeipour Day Clinic
Full name of responsible person
Sina Owlia
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Baghaeipour day clinic, Ibn Sina blvd., Safaiyeh, Yazd,
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2

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person
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<http://www.ssu.ac.ir/cms/index.php?id=16257>

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Sina Owlia
Position
Medical student
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All patient data are handled with their informed consent. No personal data, disclosing patient identities would be shared. IPD collected for the primary outcome measure only

When the data will become available and for how long

Three months after publication

To whom data/document is available

We try to publish it in an open-access journal for maximum visibility and accessibility.

Under which criteria data/document could be used

Only for academic purposes, and comparing with other studies, unidentified data would be accessible.

From where data/document is obtainable

Send an email via sinowlia@gmail.com

What processes are involved for a request to access data/document

Valid proof of academic eligibility is necessary.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Sina Owlia

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

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