Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
+98 35 3725 8410

Email address
sinowlia@gmail.com

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 capusilits 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

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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

Street address

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2

Recruitment center

Name of recruitment center

Prof. Owlia private office

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Masoud Mirzaei

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Web page address

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

Rheumatology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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