

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluating the efficacy of capsules containing pomegranate seed extract in improving the symptoms of patients with rheumatoid arthritis

Protocol summary

Study aim

Evaluating the efficacy of capsules containing pomegranate seed extract in improving the symptoms of patients with rheumatoid arthritis

Design

This is a clinical trial study with parallel groups, double-blinded randomized, will be conducted on 60 patients with rheumatoid arthritis. Assignment of patients to the study groups will be done by random numbers generation and using Excel.

Settings and conduct

This study will be performed on patients with rheumatoid arthritis referring to Golestan hospital in Ahvaz. At least 60 patients will be randomly assigned to one of two treatment groups. The patients and experimenters will not know about type of treatment and patient grouping and thus until the end of trial the study will be remained double-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of rheumatoid arthritis according to American College of Rheumatology criteria, moderate to severe rheumatoid arthritis according to DAS28 (disease Activity Score 28 (DAS-28) criteria, consent to participate in the study; Exclusion criteria: Pregnancy, renal diseases, liver diseases, respiratory diseases, taking sex hormones, cancer

Intervention groups

Intervention group: will be received 0.2 mg/kg/week methotrexate, 5 mg prednisolone 2 times a day and 200 mg pomegranate seed extract capsule 2 times a day for 2 months. Control group: will be received 0.2 mg/kg/week methotrexate, 5 mg prednisolone 2 times a day and placebo capsule 2 times a day for 2 months. (The appearance of the drug and placebo will be same).

Main outcome variables

Erythrocyte sedimentation rate (ESR), C reactive protein (CRP), Plasma level of Interleukin-17 (IL-17), Plasma level of Interleukin-6 (IL-6), count of tender joints (TJC) and swollen joints (SJC) before and after the treatment (end

of 8th week)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220828055810N1**

Registration date: **2022-11-11, 1401/08/20**

Registration timing: **prospective**

Last update: **2022-11-11, 1401/08/20**

Update count: **0**

Registration date

2022-11-11, 1401/08/20

Registrant information

Name

Ali Asghar Hemmati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3392 7310

Email address

prof.hemmati@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-04-20, 1402/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluating the efficacy of capsules containing pomegranate seed extract in improving the symptoms of patients with rheumatoid arthritis

Public title
Effect of pomegranate seed extract in rheumatoid arthritis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of rheumatoid arthritis according to American College of Rheumatology criteria Moderate to severe rheumatoid arthritis according to DAS28 (disease Activity Score 28 (DAS-28) criteria Consent to participate in the study
Exclusion criteria:
Pregnancy Renal diseases Liver diseases Respiratory diseases Taking sex hormones Cancer

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be assigned into two groups by simple randomization method. Allocation of patients to the study groups will be done by random numbers generation and using computer by excel software. Random numbers will be generated in Excel with RAND function [(=RAND()*(60))] and with this function 60 random numbers will be created in the range of 1 to 60 in a column. Each patient will be assigned a two-digit code from 01 to 60. From the beginning of the first row, move down the column of random numbers and check the first two digits of the random numbers. The first 30 people seen in our code range will be placed in the first group (intervention) and the second 30 people will place in the second group (control). A person from hospital staff, who will not responsible for patient selection, enrollment, or treatment allocation, performs the randomization. The implementation of the random allocation sequence occurs without knowledge of which patient will receive which treatment.

Blinding (investigator's opinion)
Double blinded

Blinding description
Intervention (receiving capsules containing pomegranate

seed extract or placebo) and patient evaluation will be carried out by a physician who is blinded to both treatment groups. Drug and placebo will be in similar shape, color, and taste and prepare in same capsules. Also patients and statistical analyzer will not know about patient grouping. For blinding patients, the drug and placebo are provided to patients in similar containers, which only the serial number are mentioned. At the end of the study, the serial is converted to groups A and B in Excel software. After doing statistical analysis it will be determines which group is drugs or placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz University of Medical Sciences
Street address
Golestan, Ahvaz University of medical sciences
City
Ahvaz
Province
Khouzestan
Postal code
6135733184
Approval date
2022-05-10, 1401/02/20
Ethics committee reference number
IR.AJUMS.REC.1401.163

Health conditions studied

1

Description of health condition studied
Rheumatoid Arthritis
ICD-10 code
M06.9
ICD-10 code description
Rheumatoid arthritis, unspecified

Primary outcomes

1

Description
Erythrocyte sedimentation rate (ESR)
Timepoint
before intervention and 2, 4, and 8 weeks after starting of treatment

Method of measurement

Measurement of ESR by Automated Analyser of sediment reader

2

Description

C reactive protein

Timepoint

before intervention and 2, 4, and 8 weeks after starting of treatment

Method of measurement

Using specific Kit and Immunoturbidimetry method

3

Description

Plasma level of Interleukin-17

Timepoint

before treatment and after end of treatment period

Method of measurement

By using specific laboratory Kit and ELISA reader

4

Description

Plasma level of Interleukin-6

Timepoint

before treatment and after end of treatment period (end of 8th week)

Method of measurement

By using specific laboratory Kit and ELISA reader

5

Description

count of tender joints (TJC)

Timepoint

before and after the treatment (end of 8th week)

Method of measurement

Based on the patient's symptoms and the patient's examination by a specialist

6

Description

count of swollen joints (SJC)

Timepoint

before and after the treatment (end of 8th week)

Method of measurement

Based on the patient's symptoms and the patient's examination by a specialist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patients will be received

conventional drugs including 0.2 mg/kg/week methotrexate, 5 mg prednisolone 2 times a day and 200 mg pomegranate seed extract capsule 2 times a day for 2 months. The capsule containing 200 mg of pomegranate seed extract will be prepared at the Faculty of Pharmacy of Ahvaz University of Medical Sciences

Category

Treatment - Drugs

2

Description

Control group: The patients will be received conventional drugs including will be received 0.2 mg/kg/week methotrexate, 5 mg prednisolone 2 times a day and placebo capsule 2 times a day for 2 months. The Placebo capsules (containing Contains starch, lactose and Avicel) will be prepared at the Faculty of Pharmacy of Ahvaz University of Medical Sciences. The appearance of the drug and placebo will be same.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Preofessor Ali Asghar Hemmati

Street address

Golestan Hospital, Farvardin Ave., Golestan Blvd.

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golestan.hospital@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Mehrnoosh Zaker kish

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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
 Ahvaz 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
 Ahvaz University of Medical Sciences
Full name of responsible person
 professor Ali Asghar Hemmati
Position
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Latest degree
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 Pharmacology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
 Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
 Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
 Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
 Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to

make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available