Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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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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
professor
Latest degree
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Pharmacology
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Person responsible for updating data

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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