Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

The effect of pomegranate extract on clinical index, inflammation markers and oxidative stress of Rheumatoid Arthritis patient in 1390

Protocol summary

Summary

The aim of this study is evaluate the effect of pomegranate supplement on complications in patients with Rheumatoid Arthritis, 50 Rheumatoid Arthritis patients ,aged 18-65 years old, were recruited from Shiraz Motahari Polyclinic and Ahvaz Aria hospital. The patients were randomly assigned into the two groups to receive 2 pomegranate supplements ,in the form of capsules, equal to 500 mg or placebo for 2 months. At baseline and at the end of the second month, the index of Disease activity score in 28 joints, Duration of morning stiffness, Health assessment questionnaire, Matrix metalloproteinase 3, ESR, CRP, Glutathione peroxidase and MDA and in order to controlling the confounding factors, weight, height, BMI, food frequency, disease duration, drugs type and dosage will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202183236N2**
Registration date: **2012-03-07, 1390/12/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-03-07, 1390/12/17

Registrant information

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Shiraz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source
Shiraz University of Medical Sciences

Expected recruitment start date

2011-11-22, 1390/09/01

Expected recruitment end date

2012-04-20, 1391/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pomegranate extract on clinical index, inflammation markers and oxidative stress of Rheumatoid Arthritis patient in 1390

Public title

Effect of pomegranate supplement on Rheumatoid Arthritis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Rheumatoid arthritis patients which their disease diagnosed according to the revised American Rheumatism Association criteria, ages between 18-65 years old, RA patients who don’t have enough clinical and laboratory response to conventional disease modifying anti rheumatic drugs (Methotrexate, Hydroxychloroquine, Sulphasalazine, and prednisolone), No drug type and dose fluctuation since 1 month prior to the study and during intervention period. Exclusion criteria: Presence of Chronic disease such as diabetes, cardiovascular, hepatic, kidney, gastrointestinal

diseases, and severe infection, smoking, Alcohol consumption, use of supplements (antioxidants, multivitamins,...), patients with known allergy and food intolerance.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Central Medical Building, Zand Avenue, PO Box 1978-71345

City
shiraz

Postal code

Approval date
2011-11-19, 1390/08/28

Ethics committee reference number
5811-90

Health conditions studied

1

Description of health condition studied
Rheumatoid arthritis

ICD-10 code
M06

ICD-10 code description
Other rheumatoid arthritis

2

Description of health condition studied
Rheumatoid arthritis

ICD-10 code
M05

ICD-10 code description
Seropositive rheumatoid arthritis

Primary outcomes

1

Description
Disease activity

Timepoint
Before and 2 months after intervention

Method of measurement
DAS 28

2

Description
Disability and Pain scales

Timepoint
Before and 2 months after intervention

Method of measurement
health Assessment Questionnaire for Rheumatoid Arthritis patients

3

Description
Duration of morning stiffness

Timepoint
Before and 2 months after intervention

Method of measurement
Taking history and Questionnaire

Secondary outcomes

1

Description
Glutathione peroxidase

Timepoint
Before and 2 months after intervention

Method of measurement
ELIZA kit

2

Description
MDA

Timepoint
Before and 2 months after intervention

Method of measurement
Spectrophotometry

3

Description
CRP

Timepoint
Before and 2 months after intervention
Method of measurement
ELIZA kit

4

Description
ESR
Timepoint
Before and 2 months after intervention
Method of measurement
Westergren

5

Description
MMP3
Timepoint
Before and 2 months after intervention
Method of measurement
ELIZA kit

Intervention groups

1

Description
Placebo(2 capsules) intake per day, for 2 months
Category
Placebo

2

Description
Pomegranate supplement(2 capsules) intake is equivalent to 500 mg per day, for 2 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic 2, Aria hospital
Full name of responsible person
Street address
East 17th street- Kianpars
City
Ahvaz

2

Recruitment center
Name of recruitment center
Shiraz Motahari polyclinic
Full name of responsible person
Street address
Motahari polyclinic - Namazi square-Shiraz
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research OF Shiraz university of medical sciences
Full name of responsible person
Dr. Mohammad Ali Sahmedini
Street address
Central medical building, Zand avenue
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research OF Shiraz university of medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
School of health & nutrition, Shiraz University of Medical Sciences
Full name of responsible person
Elham Tavakoli
Position
MSc student of nutrition
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

Name of organization / entity
School of health & nutrition, Shiraz University of Medical Sciences

Full name of responsible person
Dr.Zohreh Mazloom

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PHD of nutrition, assistant professor of nutrition department, Shiraz University of Medical Sciences

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty