

# 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

###### Name

Zohreh Mazloom

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1725 1008

##### Email address

zmazloom@sums.ac.ir

##### 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****Street address**

Department of nutrition, School of health & nutrition, Shiraz University of Medical Sciences

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+98 71172510018

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elham1tavakoli@yahoo.com

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## Person responsible for scientific inquiries

### Contact

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School of health & nutrition, Shiraz University of Medical Sciences

**Full name of responsible person**

Dr.Zohreh Mazloom

**Position**

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

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## Person responsible for updating data

### Contact

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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*