Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparison of the effects of soy milk and cow's milk intake on the levels of inflammatory markers, proinflammatory cytokines and oxidative stress in patients with rheumatoid arthritis

Protocol summary

Summary

The purpose of this study is evaluation the effect of soy milk intake on the levels of inflammatory markers and oxidative stress in patients with rheumatoid arthritis. This randomized crossover clinical trial was performed on 30 patients. This study had two 4-week intervention periods: 1) regular diet with soy milk (200 ml per day) and 2) regular diet with cow’s milk (200 ml per day). For putting the subjects in different groups, random sequencing generated in SPSS software was used. The wash-out period was two weeks. From the patients who received soy milk in the first intervention period was asked to replace cow's milk instead of soy milk, and vice versa. Each patient received both diets. Variables including anthropometric indicators, blood pressure, inflammatory markers and oxidative stress were measured before and after of each intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013030312689N1**
Registration date: **2013-08-02, 1392/05/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-08-02, 1392/05/11

Registrant information

Name

Razieh Choghakhori

Name of organization / entity

School of Paramedicine, Ahvaz Jondishapur University of Medical Siences

Country

Iran (Islamic Republic of)

Phone

+98 916 615 3016

Email address

choghakhori.r@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

personal

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of soy milk and cow's milk intake on the levels of inflammatory markers, proinflammatory cytokines and oxidative stress in patients with rheumatoid arthritis

Public title

effect of soymilk intake on inflammatory markers and oxidative stress

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 18-65 years old patient who have Rheumatoid Arthritis according to revised American Rheumatism Association criteria and Rheumatologist diagnosis. The type and dose of drug medication remain constant since 1 month prior and during of the study.

Exclusion criteria: Patients who have chronic disease such as diabetes, cardiovascular, hepatic, kidney, gastrointestinal diseases, and severe infection. Smoking, alcohol consumption, use of dietary supplements and having allergy to soy products or cow’s milk.

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ahvaz Jondishapur University Of Medical Sciences

Street address
Jondishapur University Of Medical Sciences, Golestan Ave. Ahvaz

City
Ahvaz

Postal code

Approval date
2012-03-03, 1390/12/13

Ethics committee reference number
NRC-9012

Health conditions studied

1

Description of health condition studied
Rheumatoid arthritis

ICD-10 code
M05

ICD-10 code description
Seropositive rheumatoid arthritis

Primary outcomes

1

Description
TNF-α

Timepoint
at baseline and end of each intervention

Method of measurement
ELISA

2

Description
IL-1

Timepoint
at baseline and end of each intervention

Method of measurement
ELISA

3

Description
hs-CRP

Timepoint
at baseline and end of each intervention

Method of measurement
ELISA

4

Description
IL-6

Timepoint
at baseline and end of each intervention

Method of measurement
ELISA

5

Description
Adiponectin

Timepoint
at baseline and end of each intervention

Method of measurement
ELISA

6

Description
Leptin

Timepoint
at baseline and end of each intervention

Method of measurement
ELISA

7

Description
RF

Timepoint
at baseline and end of each intervention

Method of measurement

Nephlometry

8

Description
MDA
Timepoint
at baseline and end of each intervention
Method of measurement
Spectrophotometric

Secondary outcomes

1

Description
Blood Pressure
Timepoint
at baseline and end of each intervention
Method of measurement
Blood Pressure Monitor

2

Description
weight
Timepoint
at baseline and end of each intervention
Method of measurement
digital scale

Intervention groups

1

Description
intervention group: daily consumption of 200 ml calcium-fortified soy milk (1% fat) for 4 weeks. produced by Soya Sun Company, in Iran.
Category
Treatment - Other

2

Description
control group: daily consumption of 200 ml cow's milk (1.5% fat) for 4 weeks. produced by Mihan-Dairy Company, in Iran.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Rheumatology Clinic of Aria Hospital
Full name of responsible person
Street address
Aria Hospital, Kianpars St. Ahvaz
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Ahvaz Jondishapur University Of Medical Sciences
Full name of responsible person
Mostafa Feghhi
Street address
Ahvaz Jondishapur University Of Medical Sciences, Golestan Ave. Ahvaz
City
Ahvaz
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, Ahvaz Jondishapur 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 Paramedicine, Ahvaz Jondishapur University Of Medical Sciences
Full name of responsible person
Razieh Choghakhori
Position
Ms. in Nutrition sciences
Other areas of specialty/work
Street address
Ahvaz Jondishapur University of Medical Sciences, Golestan Ave. Ahvaz
City
Ahvaz
Postal code
Phone
+98 61 1373 8254
Fax
Email
choghakhori.r@ajums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
School of Paramedicine, Ahvaz Jondishapur University of Medical Sciences

Full name of responsible person
Majid Mohammadshahi

Position
PhD. in Nutrition sciences

Other areas of specialty/work

Street address
Ahvaz Jondishapur University Of Medical Sciences, Golestan Ave. Ahvaz

City
Ahvaz

Postal code

Phone
+98 61 1373 8254

Fax

Email
shahi334@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
School of Paramedicine, Ahvaz Jodishapur University of Medical Sciences

Full name of responsible person
Razieh Choghakhori

Position
Ms. in Nutrition Sciences

Other areas of specialty/work

Street address
Ahvaz Jodishapur University of Medical Sciences, Golestan Ave. Ahvaz

City
Ahvaz

Postal code

Phone

Fax

Email
choghakhori.r@ajums.ac.ir

Web page address

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