# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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)

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**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
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Ms. in Nutrition sciences
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*