

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

investigating the effect of processed soy bread on serum levels of lipid profile, total antioxidant capacity and inflammatory factors in women with rheumatoid arthritis

Protocol summary

Study aim

Investigating the Effect of Soy Bread Consumption on Inflammatory Factors and Lipid Profile in Women with Rheumatoid Arthritis

Design

double blinded-randomized controlled clinical trial

Settings and conduct

Ahvaz University of Medical Sciences, after obtaining a permit to take patients from Dr. Rajaei's office, began by selecting them and randomly divided them into two groups: soy bread and wheat bread. Eat three meals a day with the main meal. The intervention will last 6 weeks. On the day of the initial test in the fasting state, they will be asked to start eating bread and will receive bread every two weeks by going to the office. At the end of the intervention, they went to the lab.

Participants/Inclusion and exclusion criteria

women with active rheumatoid arthritis that don't be in pregnant and lactation condition

Intervention groups

group1: soy bread group2:wheat bread

Main outcome variables

lipid profile, total antioxidant capacity (TAC), tumour necrosis factor- α (TNF- α), c-reactive protein (CRP)

General information

Reason for update

Acronym

RA: rheumatoid arthritis

IRCT registration information

IRCT registration number: **IRCT20181021041396N1**

Registration date: **2020-05-26, 1399/03/06**

Registration timing: **retrospective**

Last update: **2020-05-26, 1399/03/06**

Update count: **0**

Registration date

2020-05-26, 1399/03/06

Registrant information

Name

Afsaneh Sayyaf

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-12, 1398/02/22

Expected recruitment end date

2019-07-03, 1398/04/12

Actual recruitment start date

2019-05-18, 1398/02/28

Actual recruitment end date

2019-07-03, 1398/04/12

Trial completion date

2019-07-06, 1398/04/15

Scientific title

investigating the effect of processed soy bread on serum levels of lipid profile, total antioxidant capacity and inflammatory factors in women with rheumatoid arthritis

Public title

Effect of soy bread on rheumatoid arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Tendency cooperation with plan Diagnosis of rheumatoid arthritis Body mass index less than 35

Exclusion criteria:

smoking Alcohol consumption Pregnancy and lactation Having kidney, liver, gastrointestinal and heart disease and cancer Allergic reaction to processed foods Patient cancellation for study collaboration Changes in the type of medication used daily Changes in diet or physical activity for any reason Acceptance of less than 80% of interventions

Age

From **30 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **44**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization, individual Participants were divided into two groups based on the fact that the last number of their birth dates was odd and even.the persons who have even number, pose into intervention group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, bread packages will be similar, and neither patients nor researchers know the type of packages received. In fact, a third person who knows the content of the packages distributes them among the participants. The form and content of the packages are similar in the two groups, while their nature is different.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahwaz Univercity of Medical Sciences

Street address

Esfand Ave.,Golestan Blvd.,Univercity city.,Ahwaz Medical Univercity of Jondishapour

City

Ahwaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2019-05-11, 1398/02/21

Ethics committee reference number

IR.AJUMS.REC.1398.135

Health conditions studied

1

Description of health condition studied

Rheumatoid arthritis

ICD-10 code

M05

ICD-10 code description

Rheumatoid arthritis with rheumatoid factor

Primary outcomes

1

Description

Tumor necros factor Alpha

Timepoint

Before intervention and 6 week after Intervention

Method of measurement

Eliza

Secondary outcomes

1

Description

Lipid profile

Timepoint

Before intervention and 6 week after intervention

Method of measurement

Sampling from blood serum of patients

Intervention groups

1

Description

"Intervention Group:" Consumption of processed soy bread, 90 grams per day, 3 times a day with or before the main meals for 6 weeks, prepared by Sarina Company under the brand name of Dr. SOY, in Iran.

Category

Treatment - Other

2

Description

Control group: Daily consumption of 90 grams of wheat bread for 6 weeks. Prepared by Sarina Company, in Iran

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Clinic of Dr Rajaei, Scilatory of Rheumatology

Full name of responsible person

Dr. Elham Rajaei

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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Web page address**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

Dr Bijan Heli

Position

Medical Doctor,PHD

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

This is not part of purpose of present study

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