Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A study on the effect of chia seed intake inflammatory markers, joint pain severity, body weight and quality of life in patients with rheumatoid arthritis

Protocol summary

Study aim

Effect of chia seed intake on RF, CRP, ESR; inflammatory CBC indices; Anti-CCP; joint pain (VAS); disease activity (DAS28); body weight and BMI; quality of life (SF-36).

Design

A randomized controlled clinical trial with two parallel groups, single-blinded with blinding of the principal investigator and outcome assessor, will be conducted over 8 weeks in 22 patients with rheumatoid arthritis; participants will be allocated using simple randomization and a computer-generated random number table.

Settings and conduct

8-week randomized controlled, two-group, single-blind trial in rheumatoid arthritis patients at Urmia University of Medical Sciences rheumatology clinics. After informed consent, eligible patients will be randomized to chia seeds (30 g/day) or usual diet. Inflammatory markers, pain, disease activity, weight, and quality of life will be assessed at baseline and study end. Allocation and intervention distribution will be performed independently; the principal investigator and outcome assessor will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion: Confirmed RA; age 18–70 years; disease duration ≥6 months; informed consent; ability to cooperate. **Exclusion:** Inflammatory, autoimmune, infectious diseases, or cancer; omega-3 supplements, anti-inflammatory products, or herbal medicines; changes in arthritis medication; severe flare; chia allergy; pregnancy/breastfeeding.

Intervention groups

Intervention group: 30 g/day chia seeds for 8 weeks, fully soaked and consumed with yogurt, salad, or smoothie, while continuing the usual diet. Control group: No chia seeds for 8 weeks; usual diet continued.

Main outcome variables

RF; CRP; ESR; Anti-CCP; CBC inflammatory indices; pain severity (VAS); disease activity (DAS28); body weight and BMI; quality of life (SF-36)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260919071112N1**
Registration date: **2026-09-25, 1405/07/03**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-25, 1405/07/03**
Update count: **0**

Registration date

2026-09-25, 1405/07/03

Registrant information

Name

fatemeh moslemi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-23, 1405/07/01

Expected recruitment end date

2026-12-21, 1405/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study on the effect of chia seed intake inflammatory markers, joint pain severity, body weight and quality of life in patients with rheumatoid arthritis

Public title

The effect of chia seed in patients with rheumatoid arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness and informed consent to participate in the study Confirmed diagnosis of rheumatoid arthritis based on established clinical criteria Disease duration of at least 6 months Age between 18 and 70 years Ability to communicate and cooperate throughout the study period

Exclusion criteria:

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with rheumatoid arthritis will be randomly allocated to two groups: an intervention group and a control group. Participants will be assigned to the groups using a computer-generated random number table and simple randomization.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants will be randomly allocated to two groups, an intervention group and a control group, using simple randomization. The group allocation and distribution of chia seeds will be carried out by an individual independent of the principal investigator. Based on the randomization list, this individual will provide chia seeds to participants allocated to the intervention group, while no intervention will be provided to participants in the control group. To maintain blinding, the principal investigator will not have access to the group allocation and will not be informed of which group each participant has been assigned to. In addition, the outcome assessor, who will be responsible for conducting clinical assessments and measuring the study variables, will remain unaware of the participants' group assignments. Weekly follow-up and assessment of adherence to the intervention will also be conducted by the independent individual to ensure that neither the principal investigator nor the outcome assessor becomes aware of the participants' group assignments throughout the study. The group allocation codes will be kept by the independent individual until completion of the outcome assessments and will be decoded, if necessary, after the final assessments have been completed. Accordingly, participants and the intervention provider will be aware of the intervention they receive, whereas the principal investigator and outcome assessor will remain blinded to the participants' group assignments.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Roudaki St., Shahid Rezi Alley, Milan Tower, Bell 0

City

Sari

Province

Mazandaran

Postal code

4815699527

Approval date

2025-10-29, 1404/08/07

Ethics committee reference number

IR.UMSU.REC.1404.346

Health conditions studied

1

Description of health condition studied

Rheumatoid arthritis (RA)

ICD-10 code

M06.9

ICD-10 code description

Rheumatoid arthritis, unspecified

Primary outcomes

1

Description

ESR: Change in erythrocyte sedimentation rate (ESR) from baseline to the end of the 8-week intervention, measured in mm/h using the Westergren method and an

ESR reader.**CBC:** Change in complete blood count (CBC) indices from baseline to the end of the 8-week intervention, including white blood cell, red blood cell, and platelet counts and related indices, measured using the Sysmex K21N analyzer.**RF:** Change in serum rheumatoid factor (RF) level from baseline to the end of the 8-week intervention, measured using the latex method and BT1500 analyzer.**CRP:** Change in serum C-reactive protein (CRP) level from baseline to the end of the 8-week intervention, measured using the latex agglutination method and BT1500 analyzer.**Anti-CCP:** Change in serum anti-cyclic citrullinated peptide antibody (Anti-CCP) level from baseline to the end of the 8-week intervention, measured by ELISA and expressed in IU/mL.**Pain:** Change in joint pain severity from baseline to the end of the 8-week intervention, assessed using the Visual Analog Scale (VAS), scored from 0 to 10.**Disease activity:** Change in disease activity from baseline to the end of the 8-week intervention, assessed using the DAS28 score.**Weight:** Change in body weight from baseline to the end of the 8-week intervention, measured in kilograms using the InBody 770.**BMI:** Change in body mass index (BMI) from baseline to the end of the 8-week intervention, expressed in kg/m², using measurements obtained with the InBody 770.

Timepoint

Measurement of erythrocyte sedimentation rate (ESR) at baseline (before the intervention) and at the end of the 8-week intervention.

Method of measurement

Erythrocyte Sedimentation Rate (ESR): Measured using the Westergren method and an erythrocyte sedimentation rate reader after one hour, expressed in millimeters per hour.**Complete Blood Count (CBC):** Venous blood samples measured using the Sysmex K21N automated hematology analyzer, including white blood cell, red blood cell, and platelet counts and related indices.**Rheumatoid Factor (RF):** Measured using the latex agglutination method and the BT1500 analyzer.**C-Reactive Protein (CRP):** Measured using the latex agglutination method and the BT1500 analyzer.**Anti-Cyclic Citrullinated Peptide Antibody (Anti-CCP):** Serum concentration measured using the enzyme-linked immunosorbent assay (ELISA) method and expressed in international units per milliliter.**Joint Pain Severity:** Measured using the Visual Analogue Scale (VAS), consisting of a 10-cm line ranging from 0 (no pain) to 10 (worst imaginable pain).**Disease Activity:** Assessed using the Disease Activity Score in 28 joints (DAS28).**Body Weight:** Measured using the InBody 770 body composition analyzer.**Body Mass Index (BMI):** Determined based on weight and height measurements obtained using the InBody 770 body composition analyzer.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants will receive 30 g of chia seeds daily for 8 weeks. The chia seeds will be fully soaked until gel formation and consumed with yogurt, salad, or smoothie 30 minutes before the main meal. Participants will continue their usual diet throughout the study.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Medical Centers Affiliated with Urmia University of Medical Sciences

Full name of responsible person
Dr.Saeid Ghavamzadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Self-funded campus student, by the researcher, Fatemeh Moslemi
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr.saeid Ghavamzadeh
Position
Professor
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ghavamzadeh@hotmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Only a portion of the data, such as information related to the primary outcome, can be shared.
When the data will become available and for how long
One year after publication of the results.
To whom data/document is available

Researchers from academic, scientific, and research institutions, subject to approval by the researcher and compliance with data confidentiality requirements.

Under which criteria data/document could be used

Maintaining data confidentiality, using the data solely for scientific and research purposes, and not transferring the data to third parties.

From where data/document is obtainable

Applicants may submit their requests to the researcher of the study. Requests will be processed upon approval by the researcher and in accordance with the relevant regulations.

What processes are involved for a request to access data/document

Upon receipt of the applicant's request and approval by the researcher, the de-identified data or documents will be provided to the applicant within a maximum of 30 days.

Comments