Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of inulin supplementation on inflammation status, disease severity, and physical performance in patients with rheumatoid arthritis

Protocol summary

Study aim
Determining the effect of inulin supplementation on inflammation status, disease severity, and physical performance in patients with rheumatoid arthritis

Design
The clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients. A table of random numbers is used for randomization

Settings and conduct
The current study is a double-blind, randomized, placebo-controlled clinical trial that will be conducted on adult patients with rheumatoid arthritis. Patients will be randomly divided into 2 groups (30 people) to receive inulin supplement or placebo using a random numbers table. The study method will be that the blood tests of the patients, which are routinely requested by the rheumatologist for the patients in each visit, will be checked. Other variables of the study are also examined before and after the intervention (60 days)

Participants/Inclusion and exclusion criteria
Inclusion criteria include age between 30 and 65 years, completion of the consent form before starting the intervention, and not using herbal and medicinal supplements in the last three months, and non-inclusion criteria include pregnancy and breastfeeding, smoking, following a special diet, taking medications. It affects the digestive microbiome, inflammatory bowel diseases, and infectious rheumatoid arthritis, and the use of traditional medicine methods

Intervention groups
The inulin supplement and placebo will be delivered to the subjects in 10-gram packs, which will be consumed in capsule form along with a specified main meal for 60 days, along with the routine medical treatments prescribed by the doctor

Main outcome variables
Muscle strength; Morning dryness symptoms; Red blood cell sedimentation rate (ESR); CRP serum level; Disease Activity Score (DAS-28); Visual Analogue Scale (VAS); Health Assessment (HAQ)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230506058098N1**
Registration date: **2023-05-10, 1402/02/20**
Registration timing: **prospective**

Last update: **2023-05-10, 1402/02/20**
Update count: **0**

Registration date
2023-05-10, 1402/02/20

Registrant information

Name
Ali Tabatabaeyan

Name of organization / entity

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Iran (Islamic Republic of)

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+98 31 3234 0957

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-22, 1402/03/01

Expected recruitment end date
2023-12-22, 1402/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of inulin supplementation on inflammation status, disease severity, and physical performance in patients with rheumatoid arthritis

Public title
The effect of inulin on rheumatoid arthritis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 30 and 65 years Willingness to participate in the study and complete the consent form before starting the supplement therapy Not taking herbal and medicinal supplements, especially antioxidant supplements, in the three months before the start of the study

Exclusion criteria:
Pregnancy and breastfeeding smoking Following a special diet Taking drugs that affect the digestive microbiome, including antibiotics, proton pump inhibitors, and probiotic and prebiotic supplements in the last three months Inflammatory bowel diseases (Crohn's and ulcerative colitis) Using traditional medicine methods in the last 3 months Infectious rheumatoid arthritis

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Subjects will be allocated to receive the supplement or placebo using a block randomization method

Blinding (investigator's opinion)
Double blinded

Blinding description
Placebo and supplement are completely similar in appearance and will be coded by someone other than the researcher so that the researcher is not involved in the grouping process.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Esfahan University of Medical Sciences

Street address
Medical Ethics Department, 1st Floor, Building No. 3, School of Medicine, Isfahan University of Medical Sciences, Hezarjerib Street

City
Esfahan

Province
Isfehan

Postal code
8174673461

Approval date
2023-01-24, 1401/11/04

Ethics committee reference number
IR.MUI.RESEARCH.REC.1401.394

Health conditions studied

1

Description of health condition studied
Rheumatoid arthritis

ICD-10 code
M06.9

ICD-10 code description
Rheumatoid arthritis, unspecified

Primary outcomes

1

Description
Severity of rheumatoid arthritis

Timepoint
Measuring the severity of rheumatoid arthritis at the beginning of the study (before the start of the intervention) and 60 days after the start of taking the supplement (the end of the intervention)

Method of measurement
Blood tests and questionnaires related to the severity of rheumatoid arthritis

Secondary outcomes

empty

Intervention groups

1

Description

High-Performance Inulin (HPI) inulin supplement, with a degree of polymerization or DP higher than or equal to 22, under the brand name Frutafit® TEX, a product of Sensus/Netherlands, containing higher or equal to 99.5% of inulin and less than or equal to 0.5 The percentage composition of fructose, glucose, and sucrose is supplemented and prepared from Akbariye pharmaceutical importing company (Razavi Pharmaceutical Services Institute). The dosage is such that 1 capsule containing 10 grams of inulin is consumed daily for 60 days. inulin fructans; Oligo or polymer consists of D-fructose units with a glucose unit at the end. These compounds are found in foods such as celery, chicory, garlic, onions, wheat, bananas, soybeans, artichokes, and asparagus.

Category
Treatment - Drugs

2

Description
Control group: The placebo is prepared in bulk form from the domestic company "Golshehad Naqsh Jahan" and for the convenience of consumption, it is made in capsule form and distributed to the patients. The placebo is maltodextrin powder (corn starch) and is completely safe in terms of health

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Rheumatology doctor's office

Full name of responsible person
Ali Tabatabaeyan

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4th floor, Sepahan 2 building, Sepahan Alley, Amadegah St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Gholamreza Askari

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Vice Chancellor of University Research and Technology, Building No. 4, Isfahan University of Medical science, Hezarjerib St

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Marzieh Kafeshani

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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