

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 31 3234 0957

Email address

tabatabaeyanali@gmail.com

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

Isfahan

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

Street address

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

City

Esfahan

Province

Isfahan

Postal code

8134888961

Phone

+98 31 3220 0477

Email

tabatabaeyanali@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

Street address

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

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3061

Email

tabatabaeyanali@gmail.com

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

Street address

Clinical nutrition Department, 1th Floor, Faculty of Nutrition and Food Sciences, Isfahan University of Medical science, Hezarjerib St

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3169

Email

kafeshani_nut@yahoo.com

Person responsible for scientific 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

Street address

Clinical nutrition Department, 1th Floor, Faculty of Nutrition and Food Sciences, Isfahan University of Medical science, Hezarjerib St

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3169

Email

kafeshani_nut@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ali Tabatabaeyan

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

No. 93, Shojaeyan Dead End, 28th Alley, Azar St, Motahari Ave

City

Esfahan

Province

Isfahan

Postal code

8134888961

Phone

+98 31 3234 0957

Email

tabatabaeyanali@gmail.com

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