Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Investigation of the Effects of Sumac Supplementation on Disease Activity, Inflammatory Markers, and Immunomodulatory Factors in Patients with Rheumatoid Arthritis

Protocol summary

Study aim

Investigation of the Effects of Sumac Supplementation on Disease Activity, Inflammatory Markers, and Immunomodulatory Factors in Patients with Rheumatoid Arthritis

Design

Clinical trial with control group, double-blind, randomized, on 96 patients.

Settings and conduct

Rheumatoid arthritis patients referred to zarrinkob clinic in Borujerd who are eligible for the study will have a blood test once at the beginning and once after the intervention and the factors will be measured.

Participants/Inclusion and exclusion criteria

Age between 20 and 60 years; diagnosis of rheumatoid arthritis (RA) according to the American College of Rheumatology (ACR) criteria (presence of at least 4 of the following criteria for a minimum of 6 weeks: 1) morning stiffness lasting at least 1 hour, 2) arthritis in three or more joint areas, 3) arthritis of hand joints, 4) symmetric arthritis, 5) rheumatoid nodules, 6) positive rheumatoid factor, and 7) typical radiographic changes in the wrists and hands); disease duration of at least 1 year; and no changes in medication regimen during the previous 2 months.Smoking; use of nutritional or antioxidant supplements within one month prior to the study; pregnancy or lactation; history of diabetes or other chronic diseases; history of other autoimmune diseases; changes in medication regimen during the past month; and adherence to special dietary regimens.

Intervention groups

Two groups of 48 people with rheumatoid arthritis: 48 people in the group receiving 1000 mg of sumac capsules and 48 people in the group receiving placebo (lactose capsules)

Main outcome variables

hs-CRP, TNF-α, MMPs, ESR, TAC, IFN-γ, IL-17, calprotectin, zonulin, lipopolysaccharide, number of painful joints, number of inflamed joints, number of tender joints, pain; disease activity score (DAS28), joint stiffness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120415009472N30**
Registration date: **2026-06-13, 1405/03/23**
Registration timing: **prospective**

Last update: **2026-06-13, 1405/03/23**
Update count: **0**

Registration date

2026-06-13, 1405/03/23

Registrant information

Name

Naheed Aryaeian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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aryaeian.n@iums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2027-02-09, 1405/11/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation of the Effects of Sumac Supplementation on Disease Activity, Inflammatory Markers, and Immunomodulatory Factors in Patients with Rheumatoid Arthritis

Public title
The effect of Sumac on rheumatoid arthritis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20 and 60 years; diagnosis of rheumatoid arthritis (RA) according to the American College of Rheumatology (ACR) criteria (presence of at least 4 of the following criteria for a minimum of 6 weeks: 1) morning stiffness lasting at least 1 hour, 2) arthritis in three or more joint areas, 3) arthritis of hand joints, 4) symmetric arthritis, 5) rheumatoid nodules, 6) positive rheumatoid factor, and 7) typical radiographic changes in the wrists and hands); disease duration of at least 1 year; and no changes in medication regimen during the previous 2 months. The patient expresses his / her consent to participate in the study
Exclusion criteria:
Smoking; use of nutritional or antioxidant supplements within one month prior to the study; pregnancy or lactation; history of diabetes or other chronic diseases; history of other autoimmune diseases; changes in medication regimen during the past month; and adherence to special dietary regimens.
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly selected from patients referred to a rheumatologist at Zarrinkoub Clinic. After meeting the eligibility criteria, participants will be randomly allocated to either the intervention or control group using block randomization generated by STATA software. Randomization will be stratified by age (20–40 years and 40–60 years) and sex to ensure comparability between the two groups. A total of 96 eligible participants will be randomly assigned to 24 blocks of four subjects each. Random block sequences (Groups A and B) will be generated using STATA software or the Sealed Envelope randomization website and provided to the researcher.
Blinding (investigator's opinion)
Double blinded
Blinding description
Sumac or placebo will be coded by a third party who is unaware of the contents of the packages. None of the participants, nor the researcher or analyst, will be aware of the groups (sumac or placebo) and the type of intervention (sumac or placebo), and the packages containing the powder will be supplied by the company, as well as the placebo and sumac packages, in terms of internal and external appearance. After data analysis, the pharmaceutical company will be asked for the label title (drug or placebo) to compile the report and write the findings section.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Research and Technology Vice-Chancellor, Central Headquarters Building, Iran University of Medical Sciences, next to Milad Tower, Hammet Highway, Tehran
City
tehran
Province
Tehran
Postal code
14496-14535
Approval date
2026-02-02, 1404/11/13
Ethics committee reference number
IR.IUMS.SPH.REC.1404.026

Health conditions studied

1

Description of health condition studied
Patients with Rheumatoid Arthritis
ICD-10 code
Rheumatoid
ICD-10 code description

M05

Primary outcomes

1

Description
TNF-α
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

2

Description
hs-CRP
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Immunoturbidometric method

3

Description
Interferon gamma (IFN-γ)
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

4

Description
Total antioxidant capacity (TAC)
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Chromatography

5

Description
Erythrocyte sedimentation rate (ESR)
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Westergren method

6

Description
Matrix Metalloproteinases
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

7

Description
Calprotectin
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

8

Description
Interleukin-17 (IL-17)
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

9

Description
Zonulin
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

10

Description
Lipopolysaccharide
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

11

Description
Disease activity score
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Formula DAS28

12

Description
Illness severity
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Physician global assessment

13

Description
pain

Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Visual analogue scale

14

Description
Morning stiffness
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
How long (minutes) it takes for the joint dryness to go away.

15

Description
Number of painful joints
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Doctor's examination

16

Description
Tender joint counts (TJC)
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Doctor's examination

17

Description
Swollen joint count
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Doctor's examination

Secondary outcomes

1

Description
Dosage of drugs
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: 48 people in the group receiving 1000 mg of sumac capsules (3 per day, after each meal)
Category
Treatment - Drugs

2

Description
Control group: 48 people in the group receiving lactose placebo capsules (capsules made completely identical in appearance, color, smell, taste and without therapeutic effect, 3 per day, after each meal)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Zarrin Kob Clinic
Full name of responsible person
Bita Shadbakht
Street address
Behesht Square, Shahid Saremi Street, Zarinkoob Clinic
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Email
BorujerdiHospital@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Majid Safa
Street address
Vice-chancellor for Research, Iran University of Medical Sciences, Hammat Broadway
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info@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Naheed Aryaeian

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Full name of responsible person

Naheed Aryaeian

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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

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 section of the data, such as primary outcomes information or the like, will be shared.

When the data will become available and for how long

Access period start 5 months after results publishing.

To whom data/document is available

The obtained data from current study will be available only for working researchers in academic and scientific institutions

Under which criteria data/document could be used

5 months after the publicized papers from this study, the obtained data will be available to the researchers for further analysis.

From where data/document is obtainable

Applicants can be communicated to correspond author be e-mail or postal address to receive the requested data. Postal address: Nutrition Department, School of Public Health, Iran University of Medical Sciences, Hemat Highway, Tehran Cell phone: +982186704743 Email: n-aryaeian@sina.tums.ac.ir

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

Publishing in scientific-research journals Applicants will be given access to the obtained data from current study by sending an email to correspond author.

Comments