

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Rhus Coriaria (Sumac) supplementation on inflammatory status, insulin resistance and antioxidant status in patients with metabolic syndrome: a randomized, triple-blind crossover clinical intervention

Protocol summary

Study aim

The effect of sumac supplementation on inflammatory status, insulin resistance and antioxidant status in patients with metabolic syndrome: A randomized, triple-blind crossover clinical intervention

Design

A randomized, triple-blind crossover clinical intervention

Settings and conduct

Sedigheh Tahereh Research Center Random allocation method Cross-over triple blind clinical intervention

Participants/Inclusion and exclusion criteria

Inclusion criteria: Agreement to participate in the study, adults aged 20-55 years with metabolic syndrome;
Exclusion criteria: illness, taking medication and supplements, pregnancy and lactation, following a special diet

Intervention groups

Intervention group: 20 participants will consume sumac capsules (each capsule: 500 mg, 2 capsules/day) during 4 weeks.; Control group: 20 participants will consume Lactose capsules (each capsule: 500 mg, 2 capsules/day) during 4 weeks.

Main outcome variables

Inflammation status, Insulin resistance, Antioxidant status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200106046022N2**

Registration date: **2021-07-22, 1400/04/31**

Registration timing: **prospective**

Last update: **2021-07-22, 1400/04/31**

Update count: **0**

Registration date

2021-07-22, 1400/04/31

Registrant information

Name

Parvane Saneei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3792 3159

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mirenayatfatemeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Rhus Coriaria (Sumac) supplementation on inflammatory status, insulin resistance and antioxidant status in patients with metabolic syndrome: a randomized, triple-blind crossover clinical intervention

Public title

Effects of sumac on inflammatory status, insulin

resistance and antioxidant status in metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Adults 20-55 years old Metabolic syndrome based on modified ATPIII criteria

Exclusion criteria:

Having cardiovascular, liver, kidney, thyroid and diabetes diseases Pregnancy and lactation Follow a special diet Use of drugs that affect appetite, blood pressure, inflammation, fat metabolism and carbohydrates Use of multivitamin-mineral supplements, fatty acids and herbal remedies

Age

From **20 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

An unaware person that is not involved in study, will perform block randomization using the website of "WWW.randomization.com" and based on the code assigned to each participants. Such that, subjects will be randomly divided in two groups of intervention and control with a 1: 1 allocation ratio. The preparation of sumac and placebo capsules with codes A and B will be determined by a person not involved in sampling and data collection and analysis and researchers don't know how to distribute it. In each intervention period, group A will be given code A capsules and group B will be given code B capsules.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, Sumac and Lactosehr II will be replaced in single-color and uniform 500 mg capsules. Participants, researchers and statisticians will not be aware of the type of capsules

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-05-29, 1400/03/08

Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.076

Health conditions studied

1

Description of health condition studied

metabolic syndrome

ICD-10 code

E88.81

ICD-10 code description

Metabolic syndrome

Primary outcomes

1

Description

Insulin resistance (Fasting blood sugar, Insulin, HOMA-IR,QUICKI)

Timepoint

At the beginning and end of each Six-week intervention

Method of measurement

Existing commercial kits

2

Description

Antioxidant status (MDA,CTL,SOD)

Timepoint

At the beginning and end of each Six-week intervention

Method of measurement

En Existing commercial kits

3

Description

Inflammation status (CRP)

Timepoint

At the beginning and end of each Six-week intervention

Method of measurement

Existing commercial kits

Secondary outcomes

1

Description

Waist Circumference

Timepoint

At the beginning and end of each intervention period

Method of measurement

Meters irreversible

2

Description

Weight

Timepoint

At the beginning and end of each intervention period

Method of measurement

Digital Balance

3

Description

BMI

Timepoint

At the beginning and end of each intervention period

Method of measurement

Divide the weight by the square of the height

Intervention groups

1

Description

Intervention group: 500 mg capsules of sumac daily, two with food for 6 weeks in the first period of the intervention. In the second period of the intervention of this group, they are in the control group. The capsules are filled with sumac powder powdered by the researcher due to the reduction of counterfeits.

Category

Treatment - Drugs

2

Description

Control group: Lactose 500 mg capsules daily with food for 6 weeks in the first period of the intervention. In the second period of the intervention, this group is in the intervention group. The capsules are filled by the researcher with lactose.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sedigheh Tahereh Research Center

Full name of responsible person

Saneei Parvane

Street address

Sedigheh Tahereh Research Center, Khorram Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mokhtari Zeinab

Street address

School of Nutrition, Isfahan University of Medical Sciences, Hezar Jerib Ave.

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zeinab_mokhtari@yahoo.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

Parvane Saneei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Saneei Parvane

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Not applicable

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

No - There is not a plan to make this available

Data Dictionary

Not applicable