Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Rhus Coriaria(Sumac) supplementation on indicators of metabolic syndrome in adult with metabolic syndrome

Protocol summary

Study aim
Determination and comparison of anthropometric indices (weight, height, waist circumference, BMI) in the intervention and placebo groups at the beginning and end of each intervention period Determination and comparison of fasting blood sugar (FBS) in the intervention and placebo groups at the beginning and end of each intervention period Determination and comparison of lipid profile (HDL, LDL, TG, TC) between the two intervention and placebo groups at the beginning and end of each intervention period

Design
Intervention group of 20 persons Intervention: 500 mg Sumac capsule Control group of 20 people Intervention: 500 mg lactose capsule

Settings and conduct
Sedigheh Tahereh Research Center Random allocation method Cross-sectional triple blind clinical intervention

Participants/Inclusion and exclusion criteria
inclusion criteria: Willingness to participate in the study Adults 20-55 years old Metabolic syndrome Not inclusion criteria: Having the disease, taking medication and supplements, pregnancy and lactation, following a specific diet Exclusion criteria: Not willing to continue cooperation Observe the effects of supplementation Create any non-login condition

Intervention groups
Intervention group of 20 persons Intervention: 500 mg Sumac capsule Control group of 20 people Intervention: 500 mg lactose capsule

Main outcome variables
Fasting blood sugar blood pressure Waist Blood lipid profile

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200106046022N1**
Registration date: **2020-04-08, 1399/01/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-08, 1399/01/20**
Update count: **0**

Registration date
2020-04-08, 1399/01/20

Registrant information

Name
Parvane Saneei

Name of organization / entity

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Iran (Islamic Republic of)

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+98 31 3792 3159

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-04, 1398/11/15

Expected recruitment end date
2020-08-05, 1399/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of Rhus Coriaria(Sumac) supplementation on indicators of metabolic syndrome in adult with metabolic syndrome

Public title

Effects of sumac on 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

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **4**

Fasting blood samples to evaluate glucose and lipid profiles

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be divided into two groups A and B by the random blocking method 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

Tehran, Qods Town (West), between South Flamak and Zarafshan, Iran Sima St. - Central Office of Ministry of Health and Medical Education, Block A, 13th Floor

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Province

Tehran

Postal code

1111111111

Approval date

2020-03-08, 1398/12/18

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.746

Health conditions studied

1

Description of health condition studied

metabolic syndrom

ICD-10 code

E88.81

ICD-10 code description

Metabolic syndrome

Primary outcomes

1

Description

Fasting blood sugar

Timepoint

At the beginning and end of each Six-week intervention

Method of measurement

Existing commercial kits

Secondary outcomes

1

Description

Triglyceride

Timepoint

At the beginning and end of each intervention period

Method of measurement

Existing commercial kits

2

Description

High density Lipoprotein Cholesterol

Timepoint
At the beginning and end of each intervention period
Method of measurement
Existing commercial kits

3

Description
Blood pressure
Timepoint
At the beginning and end of each intervention period
Method of measurement
Barometer

4

Description
Waist size
Timepoint
At the beginning and end of each intervention period
Method of measurement
Meters irreversible

5

Description
Weight
Timepoint
At the beginning and end of each intervention period
Method of measurement
Digital Balance

6

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