# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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**

**Country**
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

**City**

Tehran

**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**
Esfahan University of Medical Sciences
**Full name of responsible person**
Mokhtari Zeinab
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**Email**
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

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## Person responsible for updating data

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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