

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### The effect of sumac and cinnamon on lipid profile and quality of life in patients with cardiovascular diseases, a randomized double-blind controlled clinical trial.

#### Protocol summary

##### Study aim

Determining the effect of sumac and cinnamon on lipid profile and quality of life in patients with cardiovascular diseases.

##### Design

A randomized clinical trial with double-blind design and parallel groups.

##### Settings and conduct

75 patients in Imam Sajjad hospital in Yasouj will be selected by the entry criteria and will be divided into 3 groups. Then, based on the list, the nurse or nutrition expert or secretary in the department will give the patients a number and a type of capsule specified for that number, and will deliver this assignment and numbering to the nutrition group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with MI between 20 and 75 years old with a BMI above 25 non-entry criteria: People who are allergic to sumac and cinnamon and suffering from systemic diseases such as liver, kidney, gout, rheumatoid arthritis and acute or chronic kidney failure.

##### Intervention groups

First intervention group: patients receiving 2 grams of sumac for 8 weeks Second intervention group: patients receiving 2 grams of sumac and cinnamon in combination for 8 weeks

##### Main outcome variables

Low density lipoprotein, high density lipoprotein, very low density lipoprotein, triglyceride, cholesterol, pain and quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150711023153N5**

Registration date: **2023-12-06, 1402/09/15**

Registration timing: **prospective**

Last update: **2023-12-06, 1402/09/15**

Update count: **0**

##### Registration date

2023-12-06, 1402/09/15

##### Registrant information

###### Name

Seyed Bahman Panahande

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 74 3322 3505

###### Email address

panahande-b@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-04-20, 1403/02/01

##### Expected recruitment end date

2024-08-20, 1403/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of sumac and cinnamon on lipid profile and quality of life in patients with cardiovascular diseases, a randomized double-blind controlled clinical trial.

##### Public title

The effect of sumac and cinnamon on cardiovascular patients

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Completing and signing the informed consent form. Age between 20-75 years Patients hospitalized in the cardiac intensive care unit who have MI (myocardial infarction) based on a definitive diagnosis. Type 2 diabetes mellitus diagnosed by a doctor Body mass index (BMI)>25 Familiarity with Persian language and the ability to read and write

**Exclusion criteria:**  
Pregnant and lactating people or people with mental illnesses, as well as patients with stomach ulcers or digestive disorders or other disorders affecting food metabolism. hypothyroidism or hyperthyroidism and any systemic disease (including liver, kidney, gout, rheumatoid arthritis and acute or chronic kidney failure) Allergy to sumac or cinnamon Users of psychotropic drugs, including antidepressants, anti-psychotics, anti-anxiety drugs Heart failure in stage IV Acute infections at the time of study entry Obstructive pulmonary diseases Treatment with sex hormones Use of medication interfering with the study Participation in another clinical study in the last 3 months People with any problems in understanding and filling the consent form

**Age**  
From **20 years** old to **75 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

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

**Sample size**  
Target sample size: **75**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients will be stratify by Block Random sampling based on age and sex in one of 12 blocks of 6 and 7 people and by random numbers from a website (Randomization.com) in one of three Sumac or Sumac and cinnamon or placebo groups, this list is in the hands of the group's secretary and Who Does not play a role in the study.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Patients, health personnel, main researchers, as well as those responsible for data collection and analysis will be unaware of the intervention and placebo groups until the end of the study. The intervention consists of placebo or sumac or sumac and cinnamon in special capsules that

are completely similar in terms of shape and color and are placed in numbered packages, and the contents of these numbers will be kept in closed envelopes in the faculty, and the contents will be preserved until the end of the study.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees of Yasuj University of Medical Science

##### Street address

Shahid Motahari Boulevard, Yasouj University of Medical Sciences

##### City

Yasuj

##### Province

Kohgilouyeh-va-Boyerahmad

##### Postal code

7591741417

#### Approval date

2023-06-10, 1402/03/20

#### Ethics committee reference number

IR.YUMS.REC.1402.040

## Health conditions studied

### 1

#### Description of health condition studied

Cardiovascular diseases (CVDs)

#### ICD-10 code

I51.6

#### ICD-10 code description

Cardiovascular disease, unspecified

## Primary outcomes

### 1

#### Description

low-density lipoprotein

#### Timepoint

At the beginning and end of the intervention period

#### Method of measurement

Laboratory methods

### 2

#### Description

high-density lipoprotein

**Timepoint**

At the beginning and end of the intervention period

**Method of measurement**

Laboratory methods - Elisa Kit

**3**

**Description**

very-low density lipoprotein

**Timepoint**

At the beginning and end of the intervention period

**Method of measurement**

Laboratory methods

**4**

**Description**

Triglyceride

**Timepoint**

At the beginning and end of the intervention period

**Method of measurement**

Laboratory methods - Elisa Kit

**5**

**Description**

Total Cholesterol

**Timepoint**

At the beginning and end of the intervention period

**Method of measurement**

Laboratory methods - Elisa Kit

**6**

**Description**

Life Quality

**Timepoint**

At the beginning and end of the intervention period

**Method of measurement**

World Health Organization quality of life questionnaire  
bref

**7**

**Description**

Pain

**Timepoint**

At the beginning and end of the intervention period

**Method of measurement**

Mcgill pain questionnaire

**Secondary outcomes**

**1**

**Description**

Interleukin-6

**Timepoint**

At the beginning and end of the intervention period

**Method of measurement**

Laboratory methods

**2**

**Description**

high sensitive C reactive protein (hs-CRP)

**Timepoint**

At the beginning and end of the intervention period

**Method of measurement**

Laboratory methods

**3**

**Description**

Complete blood count

**Timepoint**

At the beginning and end of the intervention period

**Method of measurement**

Laboratory methods

**Intervention groups**

**1**

**Description**

First intervention group: patients receiving 2 grams of sumac daily in 2 doses (1 gram capsules containing sumac).

**Category**

N/A

**2**

**Description**

Second intervention group: patients receiving daily 1 gram of sumac and 1 gram of cinnamon in 2 doses (1 gram capsules containing 0.5 grams of sumac and 0.5 grams of cinnamon)

**Category**

N/A

**3**

**Description**

Control group: patients receiving 1 gram placebo capsules (Cellulose) on 2 occasions

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Imam Sajjad hospital in Yasuj city

**Full name of responsible person**

Majid Ahmadi

**Street address**

Yasuj, road to Sajjad Hospital, Imam Sajjad Hospital

**City**

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majidahmadi1385@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Amin Hosseini Mutlaq

**Street address**

Yasouj- Shahid Motahari Boulevard- Yasuj University of Medical Sciences

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**Email**

aminhomo@yahoo.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Yasouj 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**

Yasouj University of Medical Sciences

**Full name of responsible person**

Ashkan Golmohammadi

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**

Chaharbagh Payin, 33 Alley, No. 5

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**Province**

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Seyed Bahman Panahande

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

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**City**

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**Phone**

+98 74 3322 3505

**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

Data on primary variables will be shareable after de-identifying individuals.

**When the data will become available and for how long**

The access period starts 6 months after the results are published.

**To whom data/document is available**

The data will only be available to researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

The data will only be available to researchers working in academic and scientific institutions

**From where data/document is obtainable**

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P.O. Box 7591741417, Tel:+98- 074-33346078, Fax:+98-074-33346079,

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

After receiving approval from Yasuj University of Medical Sciences (one week to one month), the data will be sent to the applicant

**Comments**