Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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+98 74 3322 3505

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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-Boyrahmad

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 questionnarie

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
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Sponsors / Funding sources

1

Sponsor
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Yasouj University of Medical Sciences
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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
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Position
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Person responsible for updating data

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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

Seyed Bahman Panahande, Yasuj University of Medical Sciences, Yasuj, Iran. Email: panahande.b@gmail.com 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