

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Feb 2026

Evaluation of the effectiveness of curcumin-piperine supplementation on inflammatory factors, cardiac biomarkers, atrial fibrillation and clinical outcomes after coronary artery bypass graft surgery (CABG): A randomized double-blind, placebo-controlled, dose-response study

Protocol summary

Study aim

Determination of the effectiveness of curcumin-piperine supplementation on inflammatory factors, cardiac biomarkers, atrial fibrillation and clinical outcomes after CABG

Design

A randomized, double-blind, clinical trial will be performed on 80 people. Randomization is done using a valid website and a 4-block method.

Settings and conduct

This clinical trial will be performed in Chamran and Sina hospitals in Isfahan. Curcumin piperine and placebo will be administered in exactly the same packages to the patient. Patients and researchers will not be aware of the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Completion of a consent form, age 30 to 80 years, gastrointestinal tract with normal function, ejection fraction above 35%, arrest time 30 to 90 minutes. Exclusion criteria: Sensitivity to herbal products such as turmeric and pepper, Herbal supplementation consumption during 3 months before surgery, need for emergency surgery, need for pump balloon, addition of other surgery, pregnancy and lactation.

Intervention groups

Intervention group 1: three capsules, each capsule containing 500 mg of curcumin and 5 mg of piperine per day. Intervention group 2: Two capsules, each capsule containing 500 mg of curcumin and 5 mg of piperine plus one placebo. Intervention group 3: One capsule containing 500 mg of curcumin and 5 mg of piperine plus two placebo capsules. Control group: 3 placebo capsules, each capsule containing 500 mg of maltodextrin per day.

Main outcome variables

Inflammatory factors, cardiac biomarkers, and atrial fibrillation. Kidney function tests (BUN, Cr)

General information

Reason for update

The type of study changed from a pilot study to a double-blind randomized clinical controlled trial.

Acronym

IRCT registration information

IRCT registration number: **IRCT20201129049534N4**
Registration date: **2021-07-13, 1400/04/22**
Registration timing: **prospective**

Last update: **2022-10-30, 1401/08/08**

Update count: **2**

Registration date

2021-07-13, 1400/04/22

Registrant information

Name

Mohammad bagherniya

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-19, 1400/05/28

Expected recruitment end date

2022-08-19, 1401/05/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of curcumin-piperine supplementation on inflammatory factors, cardiac biomarkers, atrial fibrillation and clinical outcomes after coronary artery bypass graft surgery (CABG): A randomized double-blind, placebo-controlled, dose-response study

Public title
The effects of curcumin-piperine supplementation on CABG patient

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 30-80 years Gastrointestinal normal function and with intestinal or oral nutrition criteria Ejection fraction (EF) above 15% Arrest Time (cardiac resuscitation) 30 to 90 minutes Willingness to participate in the study and complete the consent form before surgery
Exclusion criteria:
Allergy to herbal products such as turmeric and pepper Taking herbal supplements (as a supplement) during 3 months before the operation Need for emergency surgery Requires balloon pump Adding another operation in addition to CABG, like simultaneous valve operation Patients who do not have an indication for intestinal or oral nutrition on the first day of the intervention and are expected to be unable to receive intestinal or oral nutrition in the future Patients with a history of underlying disease such as congenital and immune disorders and pancreatitis Pregnancy and lactation

Age
From **30 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be divided into intervention and control groups using block classified randomization. The following authoritative site will be used to allocate the intervention in the above-mentioned manner.
<https://www.sealedenvelope.com/simple-randomiser/v1/lists> In this way, people are randomly divided into four groups of intervention and control using quadruple blocks based on age and sex.

Blinding (investigator's opinion)

Double blinded

Blinding description
For blinding the researchers, curcumin piperine and placebo capsules are purchased from Sami labs Ltd., India similar in shape, color, and size. These capsules are coded by someone other than the researchers (A and B) and the researcher distributes them without knowing the type of capsules. Patients and researchers will not be aware of the type of capsule 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
Ethics committee Vice-Chancellor in Research Affairs - Medical University of Isfahan

Street address
School of Nutrition and Food Sciences, Isfahan University of Medical Sciences, Hezar-jerib Avenue

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Postal code
8174673461

Approval date
2021-06-23, 1400/04/02

Ethics committee reference number
IR.MUI.RESEARCH.REC.1400.135

Health conditions studied

1

Description of health condition studied
Cardiovascular disease

ICD-10 code
I25.1

ICD-10 code description
Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description
C reactive Protein (CRP)

Timepoint
At baseline and end of the study

Method of measurement
ELISA test

2

Description

Blood urea nitrogen (BUN)

Timepoint

At baseline and end of the study

Method of measurement

ELISA test

3

Description

Creatinine (Cr)

Timepoint

At baseline and end of the study

Method of measurement

ELISA test

4

Description

Lactate Dehydrogenase (LDH)

Timepoint

At baseline and end of the study

Method of measurement

ELISA test

5

Description

CK-MB

Timepoint

At baseline and end of the study

Method of measurement

Commercial diagnostic kit

6

Description

Troponin

Timepoint

At baseline and end of the study

Method of measurement

Commercial diagnostic kit

Secondary outcomes

1

Description

28-days mortality rate

Timepoint

End of the study

Method of measurement

Mathematically dividing the number of dead people by the total number of people using hospital records or telephone follow-up

2

Description

Atrial fibrillation

Timepoint

End of the study

Method of measurement

Electrocardiogram (ECG or EKG)

Intervention groups

1

Description

Intervention group 1: Patients who receive three capsules containing 500 mg of curcumin and 5 mg of piperine per day for 5 days

Category

Treatment - Drugs

2

Description

Intervention group 2: Patients receiving two capsules containing 500 mg of curcumin and 5 mg of piperine for 5 days plus a placebo containing 500 mg of maltodextrin per day

Category

Treatment - Drugs

3

Description

Intervention group 3: Patients receiving one capsule containing 500 mg curcumin and 5 mg piperine for 5 days plus two placebo tablets containing 500 mg maltodextrin per day

Category

Treatment - Drugs

4

Description

Control group: Patients receiving 3 placebo capsules for 5 days, each capsule containing 500 mg of maltodextrin per day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran heart hospital

Full name of responsible person

Sahar Dadkhah Tehrani

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2

Recruitment center

Name of recruitment center

Sina heart hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

contact.organization_id

0

Name of organization / entity

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

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

Mohammad Bagherniya

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)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Study information will be published after the individuals are unidentified and after the project is completed.

When the data will become available and for how long

Access period starts six months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For further analysis

From where data/document is obtainable

Dr. Mohammad Baghernia bagherniya@nutr.mui.ac.ir

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

After reviewing the request and making it fully clear about the purposes of using the data, the data will be provided.

Comments