Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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-piperne 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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Isfahan

Province

Isfehan

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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Person responsible for updating data

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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