Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

The effect of nano-curcumin on prevention of atrial fibrillation after coronary artery bypass graft surgery: a double-blind, randomized, placebo-controlled trial

Protocol summary

Study aim
Prevention of atrial fibrillation after coronary artery bypass graft surgery and its adverse effect by curcumin

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 200 patients, simple randomization are used for randomization.

Settings and conduct
The study is being conducted in Shiraz and in Ordibehesht and Markazi hospitals. The intervention group included patients who candidate for open heart surgery and took 80 mg of curcumin-containing soft-gel nanomicell capsules three times a day for three days before surgery and four days after surgery with a standard medication regimen (including beta-blockers, statins, and aspirin, which patients had taken before surgery). they receive. The control group included patients who candidate for open heart surgery and receiving a placebo capsule three days before surgery and four days after surgery with a standard medication regimen. All patients are fully monitored for 120 hours after surgery

Participants/Inclusion and exclusion criteria
inclusion criteria: Patients are candidates for open heart surgery Have no history of heart surgery before surgery. Get medications from ACE / ARB, beta-blockers, statins and aspirin exclusion criteria: Cardiac arrhythmias or taking antiarrhythmic drugs use Digoxin Heart valve disorders Heart failure and EF ≤ 30% Renal failure (creatinine ≥ 1.5) Severe hepatic insufficiency (increased liver enzymes more than 3 times normal) Sensitivity to turmeric

Intervention groups
give curcumin to intervention group and palcebo to control group

Main outcome variables
Condition of atrial fibrillation arrhythmia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200507047327N1**
Registration date: **2020-07-21, 1399/04/31**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-21, 1399/04/31**
Update count: **0**

Registration date
2020-07-21, 1399/04/31

Registrant information

Name
Samira Hossaini Alhashemi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3242 4127

Email address
shossaini@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-25, 1399/04/05

Expected recruitment end date
2021-01-19, 1399/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of nano-curcumin on prevention of atrial fibrillation after coronary artery bypass graft surgery: a double-blind, randomized, placebo-controlled trial

Public title
effect of curcumin on prevention of atrial fibrillation after coronary artery bypass graft surgery

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who are candidates for open heart surgery No history of cardiac surgery patients use ACE/ ARB, beta blocker, statin, ASA

Exclusion criteria:
history of Cardiac arrhythmias or taking antiarrhythmic drugs use digoxin Heart valve disorders Heart failure and EF ≤ 30% Renal failure (creatinine ≥ 1.5) Severe hepatic insufficiency (increased liver enzymes more than 3 times normal) Sensitivity to turmeric

Age
From **18 years** old to **82 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants in the study are completely randomly divided into two groups of intervention and control. The method of randomization is simple, ie each participant is completely randomly assigned to one of two groups. In this way, patients receive numbers in the order that they attend the heart surgeon's office, and the odd numbers are in the control group and the even numbers are in the intervention group. Regarding the concealment of the study, it should be said that none of the participants knew about their assignment to the intervention and control groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
Three groups of people are kept blind in this study. The first group are patients who participated in the study. These people have no information about their assignment to control or intervention groups, or the type of treatment (the main drug or placebo) . The second group of patient carers in this study also do not know about the allocation of patients to the intervention and control group and the type of treatment (the main drug or placebo).The third group analyzes the data, but they do not know the nature of the data, the type of groups and the type of treatment.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences Ethics Committee

Street address
Shiraz school of pharmacy

City
Shiraz

Province
Fars

Postal code
۷۱۴۶۸۶۴۶۸۵

Approval date
2020-04-08, 1399/01/20

Ethics committee reference number
IR.SUMS.REC.1399.019

Health conditions studied

1

Description of health condition studied
cardiac disease

ICD-10 code
I25.1

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

Primary outcomes

1

Description
Condition of Atrial fibrillation arrhythmia

Timepoint
five days after open heart surgery

Method of measurement
24-hour monitoring of the patient by ECG

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: took 80 mg of curcumin-containing soft-gel nanomicell capsules three times a day for three days before surgery and five days after surgery with a standard medication regimen (including beta-blockers, statins, and aspirin, which patients had taken before surgery). they receive.

Category

Prevention

2

Description

Control group: Patients who receive placebo capsules three days before surgery and five days after surgery with a standard medication regimen.The placebo capsule is exactly like the original medicine and soft gel, which contains olive oil and is made by the main drug manufacturer (Nano Elixir Sina).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ordibehesht hospital

Full name of responsible person

Samira Hossaini Alhashemi

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Chamran street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Shiraz University of Medical Sciences Vice Chancellor for research and technology affair

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zand street

City

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7134814336

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Samira Hossaini Alhashemi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Position

resident

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person
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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
Undecided - It is not yet known if there will be 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
Clinical information of patients
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
To use the information in your next studies
From where data/document is obtainable
Samira Hossaini Alhashemi shossaini@sums.ac.ir
What processes are involved for a request to access data/document
The application is reviewed by the Shiraz University of Medical Sciences Security and may take up to 2 months
Comments