

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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  $EF \leq 30\%$  Renal failure (creatinine  $\geq 1.5$ ) Severe hepatic insufficiency (increased liver enzymes more than 3 times normal) Sensitivity to turmeric

##### Intervention groups

give curcumin to intervention group and placebo 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  $\leq$  30% Renal failure (creatinine  $\geq$  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

**Street address**

Chamran street

**City**

Shiraz

**Province**

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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

**Street address**

zand street

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Shiraz

**Province**

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**Postal code**

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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**Full name of responsible person**

Samira Hossaini Alhashemi

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

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**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

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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**