Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Investigating the use of two zinc and selenium supplements on the prevalence of atrial fibrillation after open heart surgery in patients with coronary artery disease

Protocol summary

Study aim
Determining the use of zinc and selenium supplements on the prevalence of atrial fibrillation after open heart surgery in patients with coronary artery disease in Shahid Chamran Hospital, Isfahan.

Design
A community-based, pragmatic, control group clinical trial was randomized with parallel groups.

Settings and conduct
Intervention group: they will receive daily zinc plus tablets containing 200 micrograms of selenium, 15 mg of zinc, starting one week before the operation (at the time of visiting the clinic). Control group: they will receive a placebo. The place of study will be Shahid Chamran Hospital of Isfahan. Patients of two groups after surgery in terms of clinical criteria including: atrial fibrillation through ECG, Ejection fraction (EF) before and after surgery through echocardiography, occurrence of bleeding through nursing chart in the file are checked and compared

Participants/Inclusion and exclusion criteria
Inclusion criteria are: The patient is a candidate for coronary artery bypass surgery (CABG). Cardiac ejection fraction is above 40%. Age between 40 and 70 years. Patient willingness to participate in the study. No entry conditions: History of atrial fibrillation rhythm before surgery, Combined coronary artery and heart valve surgery, Selenium and zinc deficiency, Anemia.

Intervention groups
Intervention group: They receive daily zinc plus tablets containing 200 micrograms of selenium and 15 mg of zinc, starting one week before the operation (at the time of visiting the clinic). Control group: They receive placebo tablets daily, starting one week before the operation (at the time of visiting the clinic).

Main outcome variables
Atrial fibrillation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230701058631N1**
Registration date: **2023-07-21, 1402/04/30**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-21, 1402/04/30**
Update count: **0**

Registration date
2023-07-21, 1402/04/30

Registrant information

Name
Elham Kiani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3668 1077

Email address
elhamkiani350@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-02, 1402/04/11

Expected recruitment end date
2023-08-23, 1402/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the use of two zinc and selenium supplements on the prevalence of atrial fibrillation after open heart surgery in patients with coronary artery disease

Public title
Investigating the use of two zinc and selenium supplements on the prevalence of atrial fibrillation after open heart surgery

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
The patient is a candidate for coronary artery bypass surgery (CABG). Cardiac ejection fraction is above 40% Age between 40 and 70 years Patient willingness to participate in the study

Exclusion criteria:
History of atrial fibrillation rhythm before surgery Combined coronary artery and heart valve surgery Selenium and zinc deficiency Anemia

Age
From **40 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization of patients between two groups is done using random assignment software (RA Software).The total number of sample size (72 people) and the number of groups (two groups) are entered into the software. The output of the software includes a list that randomly distributes the numbers 1 to 72 in two groups. Patients are entered into one of the two groups according to the time of visiting the hospital and according to the mentioned list, so that the sample size reaches the required number in each group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The intervention group will receive tablets with zinc and selenium compounds and the control group will receive placebo tablets. In this study, blinding is done for the patient and the evaluator and clinical caregiver.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of medical school, Isfahan University of Medical Sciences

Street address
Faculty of Medicine, Isfahan University of Medical Sciences, Hazar Jarib St., Azadi Square, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
8174675731

Approval date
2023-07-01, 1402/04/10

Ethics committee reference number
IR.MUI.MED.REC.1402.135

Health conditions studied

1

Description of health condition studied
Chronic ischemic heart disease

ICD-10 code
I25.1

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

Primary outcomes

1

Description
Atrial fibrillation

Timepoint
After surgery

Method of measurement
Electrocardiogram (ECG)

Secondary outcomes

1

Description
Ejection fraction

Timepoint
After surgery

Method of measurement
Echocardiography

2

Description

Occurrence of bleeding

Timepoint

After surgery

Method of measurement

Nursing chart on file

Intervention groups

1

Description

Intervention group: They receive daily zinc plus tablets containing 200 micrograms of selenium and 15 mg of zinc, starting one week before the operation (at the time of visiting the clinic).

Category

Prevention

2

Description

Control group: They receive placebo tablets daily, starting one week before the operation (at the time of visiting the clinic).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran Hospital, Isfahan

Full name of responsible person

Mehran Shah Zamani

Street address

Faculty of Medicine, Isfahan University of Medical Sciences, Hazar Jarib St., Azadi Square, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Roya Kelishadi

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Elham Kiani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Position
Professor

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Cardiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
No - There is not 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
No - There is not a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available