# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Effect of synbiotics versus placebo on the prevention of postoperative atrial fibrillation following coronary artery bypass grafting: A double-blind, randomized clinical trial

## Protocol summary

**Study aim**
To assess the effect of synbiotics versus placebo on the prevention of postoperative atrial fibrillation following coronary artery bypass grafting

**Design**
This is a Phase III double-blind randomized clinical trial with a control group with parallel groups, in which 242 eligible patients will be randomly assigned to the intervention and control groups using block randomization.

**Settings and conduct**
This study will be conducted at the Farshchian Heart Hospital in Hamadan, involving 242 eligible patients undergoing coronary artery bypass grafting. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Age 18–75 years, Candidate for elective coronary artery bypass grafting (CABG), Normal sinus rhythm prior to surgery, Exclusion criteria: History of prior cardiac surgery, Heart block or heart failure, Mitral or tricuspid valve disease, Hyperthyroidism, Patients with a pacemaker, Pregnancy or breastfeeding

**Intervention groups**
Intervention group: Standard treatment plus a synbiotic capsule (Familact 2 Plus), manufactured by Zist Takhmir Pharmaceutical Co., one capsule daily starting two weeks before surgery and continuing for 5 days post-surgery
Control group: Standard treatment plus a placebo capsule (containing starch), one capsule daily starting two weeks before surgery and continuing for 5 days post-surgery

**Main outcome variables**
Primary outcome: Atrial fibrillation

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20120215009014N623**
Registration date: **2026-09-16, 1405/06/25**
Registration timing: **prospective**

Last update: **2026-09-16, 1405/06/25**
Update count: **0**

**Registration date**
2026-09-16, 1405/06/25

**Registrant information**

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Jalal Poorolajal
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**Recruitment status**
**recruiting**

**Funding source**

**Expected recruitment start date**
2026-10-23, 1405/08/01

**Expected recruitment end date**
2027-04-20, 1406/01/31

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Effect of synbiotics versus placebo on the prevention of postoperative atrial fibrillation following coronary artery bypass grafting: A double-blind, randomized clinical trial

**Public title**
Effect of synbiotics versus placebo on the prevention of postoperative atrial fibrillation following coronary artery bypass grafting

**Purpose**
Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Age 18–75 years, Candidate for elective coronary artery bypass grafting (CABG), Normal sinus rhythm prior to surgery,

**Exclusion criteria:**
History of prior cardiac surgery, Heart block or heart failure, Mitral or tricuspid valve disease, Hyperthyroidism, Patients with a pacemaker, Pregnancy or breastfeeding

**Age**
From **18 years** old to **75 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**
Target sample size: **242**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
Both the medications and placebos will have the same shape. Consequently, patients will remain unaware of the type of intervention they receive. Moreover, the randomization process will be conducted by a separate individual from the one who examines the patients, ensuring that the examining person remains unaware of the intervention. Therefore, the trial will be conducted as a double-blind study.

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Hamadan University of Medical Sciences

**Street address**
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Ave

**City**
Hamadan

**Province**
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**Postal code**
6517838695

**Approval date**
2026-09-12, 1405/06/21

**Ethics committee reference number**
IR.UMSHA.REC.1405.460

## Health conditions studied

### 1

**Description of health condition studied**
Atrial fibrillation

**ICD-10 code**
I48.91

**ICD-10 code description**
Unspecified atrial fibrillation

## Primary outcomes

### 1

**Description**
Atrial fibrillation

**Timepoint**
On the first, second, third, fourth, and fifth days after surgery

**Method of measurement**
Using a monitoring device

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Standard treatment plus a synbiotic capsule (Familact 2 Plus), manufactured by Zist Takhmir Pharmaceutical Co., one capsule daily starting two weeks before surgery and continuing for 5 days post-surgery
**Category**
Treatment - Drugs

### 2

**Description**
Control group: Standard treatment plus a placebo capsule (containing starch), one capsule daily starting two weeks before surgery and continuing for 5 days post-surgery
**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Farshchian Heart Hospital in Hamadan
**Full name of responsible person**
Dr. Fatemeh Rasouli
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## Sponsors / Funding sources

### 1

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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**
Hamedan 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

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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**
Undecided - It is not yet known if there will be 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**
Undecided - It is not yet known if there will be 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**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available