

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Feb 2026

**Investigating the effect of melatonin in reducing the rate of cardiac arrhythmias during weaning from the cardiopulmonary bypass, reducing the need for sedative agents, and reducing duration of mechanical ventilation in patients undergoing coronary artery bypass graft surgery in Namazi and Shahid Faghihi Hospitals of Shiraz 2025 - 2026: a randomized, double-blinded, placebo-controlled clinical trial**

### Protocol summary

#### Study aim

Determining the effect of melatonin compared to the placebo group in reducing the rate of cardiac arrhythmias during separation from the cardiopulmonary pump, the use of sleeping pills and the duration of mechanical ventilation in patients undergoing coronary artery bypass surgery.

#### Design

Randomized, double-blind, placebo-controlled, parallel-group clinical trial of 30 patients. Eligible patients are assigned to the drug or placebo group through block randomization.

#### Settings and conduct

Location: operating room and ICU of Shahid Faqihi and Namazi hospitals in Shiraz Patients who meet the study entry criteria are randomly assigned to the drug or placebo group. Drug group, patients will receive 3 mg of melatonin tablets for 3 nights before the operation until the end of the day when they are in the cardiac surgery intensive care unit. The control group receives placebo instead of melatonin while maintaining all the conditions of the intervention group

#### Participants/Inclusion and exclusion criteria

Age over 30 years, coronary artery transplant surgery with cardiopulmonary pump and absence of uncontrollable underlying diseases

#### Intervention groups

In the intervention group, patients will receive 3 mg of melatonin tablets (physiological dose) for 3 nights before the operation until the end of the day they are in the cardiac surgery intensive care unit. The control group receives placebo instead of melatonin while maintaining all the conditions of the intervention group.

#### Main outcome variables

Dose of intravenous sedatives, cardiac arrhythmia, duration of mechanical ventilation, length of stay in ICU

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20250206064666N1**

Registration date: **2025-02-24, 1403/12/06**

Registration timing: **prospective**

Last update: **2025-02-24, 1403/12/06**

Update count: **0**

#### Registration date

2025-02-24, 1403/12/06

#### Registrant information

##### Name

Bahare Firouzbakht

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3647 4254

##### Email address

bfirouzbakht@sums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2025-04-21, 1404/02/01  
**Expected recruitment end date**  
2025-10-23, 1404/08/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

#### **Scientific title**

Investigating the effect of melatonin in reducing the rate of cardiac arrhythmias during weaning from the cardiopulmonary bypass, reducing the need for sedative agents, and reducing duration of mechanical ventilation in patients undergoing coronary artery bypass graft surgery in Namazi and Shahid Faghihi Hospitals of Shiraz 2025 - 2026: a randomized, double-blinded, placebo-controlled clinical trial

#### **Public title**

Investigating the effect of melatonin in patients undergoing coronary artery bypass surgery

#### **Purpose**

Prevention

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Elective coronary artery bypass surgery using on-pump (CABG) in Shahid Faqihi and Namazi hospitals in Shiraz  
Age above 30 years ASA: 1-3 GCS:15

##### **Exclusion criteria:**

Age less than 30 years Emergency surgery Valve surgery at the same time as coronary artery bypass surgery Off-pump surgery More than 4 coronary artery grafts Previous history of any cardiac arrhythmia Having a pacemaker Local or systemic infection Heart failure with an ejection fraction of less than 30% Uncontrolled blood pressure and diabetes History of seizures History of recent or chronic use of psychiatric drugs, sleeping pills, alcohol and melatonin Severe liver, kidney and lung diseases inability to speak malignancy Pregnancy and breastfeeding Allergy to melatonin

#### **Age**

From **30 years** old

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

#### **Sample size**

Target sample size: **30**

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

Randomized

#### **Randomization description**

The randomization of the samples will be based on the block randomization method. Blocks of four are generated using the website dedicated to this calculation

(<https://www.sealedenvelope.com/simple-randomiser/v1/lists>). Each of the patients entering the study will be assigned a code, and the type of group that should take medicine or placebo will be determined.

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

After the preparation of melatonin tablets (manufactured by Aria Daru Company, Iran) and placebo (completely similar to the drug in terms of size and color, manufactured by the Faculty of Pharmacy of Shiraz University of Medical Sciences), the drug or placebo with a specified number for one patient is placed in a similar package by the project manager, and the specific code of each patient is inserted on the package. The patient, the data collector and the interventionist do not know about the distribution of patients in the two drug and placebo groups until the completion of the study and the disclosure of its codes.

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

###### **Street address**

Building No. 3, Shiraz Faculty of Medicine, Imam Hossein Square, Zand St.

###### **City**

Shiraz

###### **Province**

Fars

###### **Postal code**

7134845794

##### **Approval date**

2025-02-05, 1403/11/17

##### **Ethics committee reference number**

IR.SUMS.REC.1403.494

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Coronary artery disease

##### **ICD-10 code**

I25.1

##### **ICD-10 code description**

Atherosclerotic heart disease of native coronary artery

## Primary outcomes

### 1

#### Description

Dose of intravenous hypnotic drug

#### Timepoint

The first day after surgery

#### Method of measurement

Patient file

### 2

#### Description

Cardiac arrhythmia

#### Timepoint

During weaning from the cardiopulmonary pump

#### Method of measurement

Observation

### 3

#### Description

Duration of using mechanical ventilation

#### Timepoint

After surgery

#### Method of measurement

Observation

## Secondary outcomes

### 1

#### Description

Mortality

#### Timepoint

Until discharge from ICU

#### Method of measurement

counting

### 2

#### Description

Length of stay in ICU

#### Timepoint

At the time of discharge from the ICU

#### Method of measurement

Counting

## Intervention groups

### 1

#### Description

Intervention group: In the intervention group, patients will receive 3 mg of melatonin tablets for 3 nights before the operation until the end of the day when they are in the cardiac surgery intensive care unit.

#### Category

Treatment - Other

### 2

#### Description

Control group: The control group receives placebo instead of melatonin while maintaining all the conditions of the intervention group

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Namazi Hospital

##### Full name of responsible person

Bahare Firouzbakht

##### Street address

Namazi Blvd

##### City

Shiraz

##### Province

Fars

##### Postal code

7193613311

##### Phone

+98 71 3647 4332

##### Email

nemazee\_inf@sums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Shahid Faghihi Hospital

##### Full name of responsible person

Bahare Firouzbakht

##### Street address

Karim Khan Zand Blvd

##### City

Shiraz

##### Province

Fars

##### Postal code

7134846114

##### Phone

+98 71 3235 1087

##### Email

FaghihiHsp@Sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Hamid Mohammadi

##### Street address

Karim Khan Zand Boulevard, Research and

Technology Vice-Chancellor, Shiraz University of  
Medical Sciences

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vcrdep@sums.ac.ir

**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**

Bahare Firouzbakht

**Position**

Instructor

**Latest degree**

Master

**Other areas of specialty/work**

Cardiovascular Perfusion

**Street address**

School of Nursing and Midwifery, Karim Khan Zand  
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## Person responsible for scientific inquiries

**Contact**

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**Position**

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**Other areas of specialty/work**

Anesthesiology

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## Person responsible for updating data

**Contact**

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Shiraz University of Medical Sciences

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Confidentiality of patient information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available  
**Clinical Study Report**  
No - There is not 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