

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/ists>). 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

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7193613311

Phone

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hamid Mohammadi

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Karim Khan Zand Boulevard, Research and

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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

Bahare Firouzbakht

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Cardiovascular Perfusion

Street address

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**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

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Full name of responsible person

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Position

Instructor

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

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Position

Instructor

Latest degree

Master

Other areas of specialty/work

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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