Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The prophylactic effect of oral Melatonin on cardiac and inflammatory biomarkers after Artery Bypass Grafting Surgery (CABG) on pump technique

Protocol summary

Study aim
The prophylactic effect of oral Melatonin on cardiac and inflammatory niomarkers after Artery Bypass Grafting (CABG) surgery on pump technique

Design
Clinical trial with control group, Parallel group, Double blinded, randomized phase 3 with 74 patients, Randomization using permuted blocks

Settings and conduct
Patients undergoing coronary artery bypass graft surgery at Shahid Mohammadi Hospital in Bandar Abbas will be enrolled in the study and will be randomly allocated to the intervention and control groups using a permuted-block randomization method. The participants and the data analyst will be blinded (double-blind).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients who are candidates for elective coronary artery bypass surgery, age 30 to 80 years, anesthesia class 2 and 3, not receiving analgesics within 6 hours before surgery, and cardiac ejection fraction greater than 40 percentage. Exclusion criteria: Unwillingness to participate in the research project.

Intervention groups
Patients in the intervention group receive oral melatonin tablets (3 mg, Razak Company, Iran) 12 hours before surgery and on the morning of surgery. All patients are evaluated for anesthesia one day before surgery, after arrival in the operating room undergo standard monitoring, and their baseline hemodynamic parameters are recorded. Patients in the control group receive oral placebo tablets (3 mg, Dara Kimia Aria Company, Iran) 12 hours before surgery and on the morning of surgery.

Main outcome variables
C-Reactive Protein; Erythrocyte Sedimentation Rate; Cardiac Troponin; Creatine Kinase–Myocardial Band; Systolic Blood Pressure; Diastolic Blood Pressure; Mean Arterial Pressure; Lactate Dehydrogenase; Interleukin-6

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260513069384N1**
Registration date: **2026-08-06, 1405/05/15**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-06, 1405/05/15**
Update count: **0**

Registration date
2026-08-06, 1405/05/15

Registrant information

Name
Farzaneh Akhtari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7733 0012

Email address
farzaneh@hums.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-07-23, 1405/05/01

Expected recruitment end date
2027-06-10, 1406/03/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The prophylactic effect of oral Melatonin on cardiac and inflammatory biomarkers after Artery Bypass Grafting Surgery (CABG) on pump technique

Public title
Effect of Melatonin on cardiac biomarkers

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patient candidate for Coronery Artery Bypass Grafting(CABG) surgery Patients aged 30 to 80 years Patients with anesthesia class 2 and 3 No receiving analgesic during 6 hours before surgery Patients with ejection fraction greater than 40 percent Patients without a history of renal, hepatic, gastrointestinal disease, or pulmonary failure No addiction to alcohol or narcotic drugs

Exclusion criteria:
No willingness to participate in the research project

Age
From **30 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
The study employs a permuted block randomization method. To this end, two treatment groups, A and B, were defined as AB and BA blocks. Random numbers were generated within the range of 0 to 9, where numbers 0–4 were assigned to the AB block, and 5–9 were assigned to the BA block. Upon selecting a random number from the table, if the number falls within 0–4, the AB block is assigned; consequently, the next two participants are enrolled, with the first receiving treatment A and the second receiving treatment B. This procedure is repeated systematically to assign treatment groups for subsequent participants. Although this method ensures an equal number of observations in both groups, the small block size poses a risk of treatment allocation predictability by the investigator. To mitigate this, the randomization list is generated prior to the commencement of the study by an independent, blinded individual who is not involved in the clinical care of the participants.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this double-blind clinical trial, in order to maintain blinding, capsules containing melatonin and placebo before the start of the study were prepared by an independent person outside the research team in identical packages in terms of shape, color, and label and were randomly labeled with codes A and B. The coding key is kept only by this independent person and remains confidential until the completion of statistical analysis and finalization of the results. Allocation of participants to the groups is performed based on these codes. The participants, the principal investigator, and the clinical caregivers (including the treating resident) are unaware of the type of the allocated intervention (melatonin or placebo). Outcome assessment and biomarker measurement are performed by laboratory personnel who are also unaware of the group allocation and the type of intervention. Data analysis is performed by the researcher using coded data (A and B), without access to the coding key. Unblinding of the codes is performed only after completion of the statistical analysis.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hormozgan University of Medical Sciences

Street address
Shahid Chamran Boulevard, Ghadeer Boulevard

City
Bandarabbas

Province
Hormozgan

Postal code
7916613885

Approval date
2026-01-27, 1404/11/07

Ethics committee reference number
IR.HUMS.REC.1404.351

Health conditions studied

1

Description of health condition studied
Coronary artery disease with an indication for coronary artery bypass surgery

ICD-10 code
I25.10

ICD-10 code description
Atherosclerotic heart disease of native coronary artery without angina pectoris

Primary outcomes

1

Description
Creatine Kinase–Myocardial Band
Timepoint
Before the intervention and two days after completion of the intervention
Method of measurement
immunoassay

2

Description
Troponin
Timepoint
Before the intervention and two days after completion of the intervention
Method of measurement
immunoassay

Secondary outcomes

1

Description
Erythrocyte Sedimentation Rate
Timepoint
Before the intervention and two days after completion of the intervention
Method of measurement
Westergren method

2

Description
C-reactive protein serum level
Timepoint
Before the intervention and two days after completion of the intervention
Method of measurement
Enzyme-Linked Immunosorbent Assay methode

3

Description
Lactate Dehydrogenase serum level
Timepoint
Before the intervention and two days after completion of the intervention
Method of measurement
Spectrophotometer

4

Description
Interleukine-6 serum level
Timepoint
Before the intervention and two days after completion of the intervention
Method of measurement
Enzyme-Linked Immunosorbent Assay methode

5

Description
White blood cells count
Timepoint
Before the intervention and two days after completion of the intervention
Method of measurement
Cell counter(hematology analyzer)

6

Description
Platelet count
Timepoint
Before the intervention and two days after completion of the intervention
Method of measurement
Cell counter(hematology analyzer)

7

Description
Hemoglobin level
Timepoint
Before the intervention and two days after completion of the intervention
Method of measurement
Cell counter(hematology analyzer)

8

Description
Mean arterial pressure
Timepoint
Before surgery, every half hour during surgery, and after being transferred to the intensive care unit every two hours
Method of measurement
Arterial catheter

9

Description
Systolic blood pressure
Timepoint
Before surgery, every half hour during surgery, and after being transferred to the intensive care unit every two hours
Method of measurement
Arterial catheter

10

Description
Diastolic blood pressure
Timepoint
Before surgery, every half hour during surgery, and after being transferred to the intensive care unit every two hours
Method of measurement
Arterial catheter

11

Description
Aortic clamp time
Timepoint
During surgery
Method of measurement
Measuring time with a timer and recording it by the anesthesia assistant

12

Description
Cardiopulmonary pump duration
Timepoint
During surgery
Method of measurement
Measuring time with a timer and recording it by the anesthesia assistant

13

Description
Need for inotropes
Timepoint
During surgery and after surgery
Method of measurement
Recorded by the anesthesia assistant

14

Description
Extubation time
Timepoint
After the surgery and moving the patient to the intensive care unit
Method of measurement
Recorded by the anesthesia assistant (by hour)

Intervention groups

1

Description
Intervention group: Patients in this group, consisting of 37 individuals, receive one oral melatonin tablet of 3 milligrams manufactured by Razak Company,Iran, 12 hours before surgery, and then on the morning of the day of surgery, they take the second dose, which is another 3 milligram melatonin tablet, orally. Therefore, the total dose received by these patients is 6 milligrams of melatonin administered in two doses. After the patient is transferred to the operating room, standard monitoring, including a non-invasive blood pressure cuff (NIBP), pulse oximetry, and electrocardiography (ECG), is applied, and baseline hemodynamic parameters, including systolic blood pressure, diastolic blood pressure, mean arterial pressure, and heart rate, are recorded. Then the radial artery of the patient's non-dominant hand is anesthetized with 2 percent lidocaine and cannulated with a size 20 pink angiocatheter in order to monitor arterial pressure invasively. Induction of anesthesia is performed with etomidate (0.2 milligrams per kilogram), cisatracurium (0.2 milligrams per kilogram), and fentanyl (10 micrograms per kilogram), and the surgical procedure is started. Maintenance of anesthesia during the operation is carried out using infusion of propofol, atracurium, and sufentanil. The patient receives heparin at a dose of 3 milligrams per kilogram, and after the activated clotting time reaches more than 480, the patient is placed on cardiopulmonary bypass. During the surgery, hemodynamic parameters are recorded every 30 minutes by an anesthesia resident who is unaware of the type of intervention and the patient's group allocation. In addition, the duration of cardiopulmonary bypass, the duration of aortic cross-clamping, and the need for inotropic agents are documented in the researcher's questionnaire. After completion of the surgery, the patient is transferred to the intensive care unit with full monitoring. At this stage, hemodynamic parameters are recorded every 2 hours, and the time to extubation and the duration of the patient's stay in the intensive care unit are documented by the same anesthesia resident who is unaware of the group allocation. On the second postoperative day, a second blood sample is obtained to measure the inflammatory and cardiac biomarkers again so that they can be compared with the baseline values.
Category
Treatment - Drugs

2

Description
Control group: This group consists of 37 patients. Instead of melatonin, they receive an oral 3-mg sucralose (sugar) tablet manufactured by Dara Kimia Aria, Iran, 12 hours before surgery, with a second oral dose administered on the morning of surgery. The timing of these two doses is identical to that of the intervention group.All subsequent procedures for this group are performed exactly as in the intervention group: application of standard monitoring and recording of baseline parameters upon arrival in the operating room, radial artery cannulation using the same technique, induction of anesthesia with the same agents and doses (etomidate, cisatracurium, and fentanyl), maintenance of anesthesia with the same drug regimen (propofol, atracurium, and sufentanil), and heparinization using the same dose and target activated clotting time (ACT). Intraoperative hemodynamic parameters (recorded every 30 minutes) and ICU hemodynamic parameters (recorded every 2 hours), as well as cardiopulmonary bypass duration, aortic cross-clamp time, inotropic support requirements, extubation time, and ICU length of stay, are recorded by the same anesthesia resident, who is blinded to group allocation, using the same procedures as those applied in the intervention group. Blood samples for biomarker assessment are also collected at the same two time points (baseline and postoperative day 2).
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Mohamadi Hospital
Full name of responsible person
Hashem jarineshin
Street address
Opposite the Health Center, Beltway Road, Islamic Republic Boulevard.
City
Bandarabbas
Province
Hormozgan
Postal code
7919915519
Phone
+98 21 7733 0012
Email
hjarineshin@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Shahram zare
Street address
Shahid Chamran Boulevard, Ghadeer Boulevard
City
Bandarabbas
Province
Hormozgan
Postal code
7951674852
Phone
+98 21 7733 0012
Email
shzare159@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Bandare-abbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Farzaneh Akhtari
Position
Anesthesia resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Shahid Chamran Boulevard, Ghadeer Boulevard
City
Bandarabas
Province
Hormozgan
Postal code
7951674852
Phone
+98 21 7733 0012
Fax
Email
farzaneh@hums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Farzaneh Akhtari
Position
Anesthesia resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Shahid Chamran Boulevard, Ghadeer Boulevard
City
Bandarabas
Province
Hormozgan
Postal code
7951674852
Phone
+98 21 7733 0012
Fax
Email
farzaneh@hums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Farzaneh Akhtari

Position
Anesthesia resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Shahid Chamran Boulevard, Ghadeer Boulevard
City
Bandarabas
Province
Hormozgan
Postal code
7951674852
Phone
+98 21 7733 0012
Fax
Email
farzaneh@hums.ac.ir

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