Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The investigation of the effects of melatonin supplement on the rate of postoperative artrial fibrillation after coronary artery bypass grafting sutgery

Protocol summary

Study aim

Investigating the effect of melatonin supplementation on the prevention of atrial fibrillation in patients undergoing coronary artery bypass surgery

Design

This study is a controlled, parallel-group, triple-blind, randomized, phase 3 clinical trial on 154 patients. Random allocation chain to groups will be prepared using Random allocation software

Settings and conduct

Randomization based on random blocks; triple blinding strains are selected for Doctors, Researchers, Patients, etc., Patients who will undergo CABG surgery in the next 5 days at Shahid Rajaei Karaj hospital.Patients in the drug group receive Melatonin from 3 days before surgery and up to 5 days after. Control group patients also receive placebo in the same way. Patients are examined in a period of 8 days In the form of clinical examinations and questionnaires.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients 18 years or older who are candidates for coronary artery transplantation Exclusion critria: People with a history of atrial fibrillation;history of allergic reaction to melatonin;inability to swallow;with unstable hemodynamics; concurrent valve surgery; emergency surgery; history of any supraventricular arrhythmia; use of antiarrhythmic drugs; kidney failure; chronic liver disease; pregnancy and breastfeeding

Intervention groups

A control group receiving standard of care plus placebo and a study group receiving standard of care plus oral melatonin 10 mg nightly from 3 days before surgery to 5 days after surgery

Main outcome variables

Primary outcome: rate of postoperative atrial fibrillation in the first 5 days after coronary artery bypass surgery Secondary outcome: examination of CK-MB level and increased troponin and hs-CRP; duration of POAF; The duration of hospitalization of patients in the intensive care unit and hospital

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230902059320N1**
Registration date: **2023-10-14, 1402/07/22**
Registration timing: **prospective**

Last update: **2023-10-14, 1402/07/22**
Update count: **0**

Registration date

2023-10-14, 1402/07/22

Registrant information

Name

Pantea Parandeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4415 5238

Email address

p.parandeh.pharmacist@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-22, 1402/07/30

Expected recruitment end date

2024-10-21, 1403/07/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The investigation of the effects of melatonin supplement on the rate of postoperative artrial fibrillation after coronary artery bypass grafting sutgery

Public title
The investigation of the effects of melatonin on the rate of postoperative artrial fibrillation after coronary artery bypass grafting sutgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18 years or older, whose blood supply disorder to the heart makes them candidates for coronary artery baypass grafting surgery Signing the consent form by the patient or the patient's qualified companion
Exclusion criteria:
People with a history of atrial fibrillation People with a history of allergic reactions to melatonin or other ingredients in the tablet People with the inability to swallow the oral form of melatonin in tablet form People with unstable hemodynamics before surgery People undergoing heart valve surgery at the same time Emergency coronary artery bypass surgery People with a previous history of any supraventricular arrhythmia Use of antiarrhythmic drugs People with kidney failure People with chronic liver disease Pregnant or lactating women
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **154**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization based on random blocks (Permuted Block Randomization) Unit of randomization: Individual patients Randomization tool: Sealed envelope containing intervention group By using random block tables, 39 blocks of 4 members according to a total of approximately 154 sample size will be chosen. Within each block there will be 2 Interventions and 2 placebos. Permutations will be random and allocation to the study groups will be applied by using sealed envelope. Patients and medical providers will be unaware of the randomization scheme and study groups.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Healthcare Personnel (Includeincludeing Doctors, Nurses), Students (Principal Researcher), Participants, and the Person Evaluating the Results and the Analyst Do not Know About Receiving the Drug or Placebo. A Concealment envelope will assign patients to intervention group according to random block table. Melatonin and placebo capsule will be identical for keeping patients and medical providers blinded.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Alborz University of Medical Sciences
Street address
No.1, Alley 31.,South Parvaneh St.,Ferdous Gharb Blvd.,Tehran Town
City
Alborz
Province
Alborz
Postal code
148363788603
Approval date
2023-06-24, 1402/04/03
Ethics committee reference number
IR.ABZUMS.REC.1402.099

Health conditions studied

1

Description of health condition studied
Atrial fibrillation
ICD-10 code
I48.0
ICD-10 code description
Paroxysmal atrial fibrillation

Primary outcomes

1

Description
Percentage of people who suffer from atrial fibrillation after coronary artery bypass surgery
Timepoint
The incidence of atrial fibrillation after surgery in the first five days after CABG surgery

Method of measurement
Atrial fibrillation is diagnosed based on the absence of distinct repetitive P waves followed by irregular RR intervals lasting at least 30 seconds on a 12-lead ECG obtained from the patient.

Secondary outcomes

1

Description
Examining the levels of CK-MB enzyme; troponin protein and hs-CRP
Timepoint
From one day before the operation to the first 5 days after the operation
Method of measurement
Checking the results of laboratory measurements and the information recorded in the patient's file

2

Description
Duration of atrial fibrillation after surgery
Timepoint
Daily from the day after surgery
Method of measurement
Counting the number of days a person has atrial fibrillation after coronary artery bypass surgery and recording information based on the patient's file

3

Description
Duration of hospitalization in the intensive care unit
Timepoint
Daily from the day after surgery
Method of measurement
Counting the number of days a person is hospitalized in the intensive care unit of the hospital after surgery and based on the patient's admission file

4

Description
Duration of hospitalization
Timepoint
Daily from the day after surgery
Method of measurement
Counting the number of days a person is hospitalized and based on the patient's admission file

Intervention groups

1

Description
Patients receiving melatonin 10 mg tablets at night, 1 tablet from 3 days before surgery to 5 days after surgery
Category
Prevention

2

Description
Control group: Patients receiving placebo, 1 tablet at night from 3 days before surgery to 5 days after surgery
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rejaei Hospital
Full name of responsible person
Pantea Parandeh
Street address
No.1,Alley 31., South Parvaneh St., Ferdous Gharb Blvd.,Tehran Town
City
Alborz
Province
Alborz
Postal code
1483637886
Phone
+98 21 4415 5238
Email
P.Parandeh.Pharmacist@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Pantea Parandeh
Street address
No. 1,Alley 31., South Parvaneh St.,Ferdous Gharb Blvd., Tehran Town
City
Alborz
Province
Alborz
Postal code
1483637886
Phone
+98 21 4415 5238
Email
P.Parandeh.Pharmacist@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Karaj 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
Karaj University of Medical Sciences
Full name of responsible person
Pantea Parandeh
Position
Pharmacy student
Latest degree
A Level or less
Other areas of specialty/work
Medical Pharmacy
Street address
No. 1,Alley 31,South Parvaneh St., Ferdous Gharb Blvd.,Tehran Town
City
Tehran
Province
Tehran
Postal code
1483637886
Phone
+98 21 4415 5238
Email
P.Parandeh.Pharmacist@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Pantea Parandeh
Position
pharmacy student
Latest degree
A Level or less
Other areas of specialty/work
Medical Pharmacy
Street address
No. 1,Alley 31., South Parvaneh St.,Ferdous Gharb Blvd., Tehran Town
City
Tehran
Province
Tehran
Postal code
1483637886
Phone
+98 21 4415 5238
Email
P.Parandeh.Pharmacist@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Pantea Parandeh
Position
Pharmacy student
Latest degree
A Level or less
Other areas of specialty/work
Medical Pharmacy
Street address
No. 1,Alley 31., South Parvaneh St.,Ferdous Gharb Blvd., Tehran Town
City
Tehran
Province
Tehran
Postal code
1483637886
Phone
+98 21 4415 5238
Email
P.Parandeh.Pharmacist@gmail.com

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
Not applicable
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