Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Feb 2026

Investigating the Effect of Melatonin Supplement on the Incidence of Delirium in Patients Undergoing Coronary Artery Bypass Graft Surgery in a Three-blind, Placebo-controlled Clinical Trial.

Protocol summary

Study aim

Determining the effect of Melatonin supplement in preventing Delirium in patients undergoing Coronary Artery Bypass Graft Surgery

Design

A controlled, Parallel-group, Triple-blind, Randomized, Phase 3 clinical trial on 146 patients. Randomized blocks were used for randomization.

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 and older who are undergoing CABG surgery; Sign the consent form - Exclusion Criteria: History of allergic reaction to Melatonin; History of mental disorders; Severe Kidney and Liver failure; Suffering from Alzheimer's; History of Seizures; History of Delirium; Alcohol or drug addiction; Unable to swallow pills; Pregnant and Lactating women

Intervention groups

Demographic information of the patient will be recorded in all patients who enter the study. Patients in the drug group receive one 10 mg Melatonin tablet at night 1 hour before going to bed from 3 days before surgery and up to 5 days after surgery. Control group patients also receive placebo in the same way. All CAM-ICU, CAM-S, GCS, ESS, NRS questionnaires are performed by the researcher for all patients to check the Effectiveness of Melatonin in preventing Delirium.

Main outcome variables

The amount, Duration and Intensity of Delirium after surgery during the first 5 days; Duration of hospitalization of patients in ICU and hospital; Evaluation of patients' sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230820059193N1**
Registration date: **2023-08-30, 1402/06/08**
Registration timing: **prospective**

Last update: **2023-08-30, 1402/06/08**
Update count: **0**

Registration date

2023-08-30, 1402/06/08

Registrant information

Name

Fatemeh Sarbakhsh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 4464 7794

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Melatonin Supplement on the Incidence of Delirium in Patients Undergoing Coronary Artery Bypass Graft Surgery in a Three-blind, Placebo-controlled Clinical Trial.

Public title

Investigating the effect of Melatonin supplement on the incidence of Delirium After Coronary Artery Bypass Graft surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 18 years of age, whose blood supply disorder to the heart makes them candidates for Coronary Artery Bypass Graft surgery Patients who have no problem understanding Persian language Signing the consent form by the patient (Consent is obtained from patients in written and verbal form)

Exclusion criteria:

People who have a history of allergic reaction to Melatonin or other ingredients in the pill Patients who suffered cardiac and respiratory arrest Patients who Have a history of mental disorders such as Psychosis and Mental Retardation Patients who take Antipsychotic drugs Patients with a history of Seizures Patients with a history of Delirium Patients with Alzheimer's Patients with severe Kidney and Liver failure Patients with Alcohol or drug addiction Patients who need reoperation due to abnormal bleeding Patients who are deaf Patients who do not have the ability to speak to answer the questions in the questionnaire Patients who are unable to swallow oral Melatonin Patients who are candidates for emergency surgery Pregnant and Lactating women If older people had medicines that interfered with my research Older people who are not able to participate in this plan for any reason

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **146**

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced randomization by using random blocks. Unit of randomization: Individual patients Randomization tool: Sealed envelope containing intervention group By using random block tables, 37 blocks of 4 members according to a total of approximately 146 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 (Including 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

2th floor, Research and Technology Deputy Bldg, Research Ethics Office, 45 meter Golshahr, Shahid Safarian Alley

City

Karaj

Province

Alborz

Postal code

3198764653

Approval date

2023-08-12, 1402/05/21

Ethics committee reference number

IR.ABZUMS.REC.1402.142

Health conditions studied

1

Description of health condition studied

Incidence of Delirium After Coronary Artery Bypass Surgery

ICD-10 code
F05.8
ICD-10 code description
Postoperative delirium

Primary outcomes

1

Description
The rate of Delirium after surgery during the first 5 days after surgery
Timepoint
Investigation and recognition of confusion and monitoring of Delirium in patients of special care department is done on the day of operation and up to two days after the operation.
Method of measurement
The confusion assessment-special care (CAM-ICU) questionnaire is used to investigate and recognize confusion and monitor delusions.

Secondary outcomes

1

Description
Measuring the intensity of delirium
Timepoint
After the diagnosis of delirium until two days after the operation, its severity is checked further.
Method of measurement
Confusion Assessment Method-severity (CAM-S) questionnaire

2

Description
Measuring the level of alertness and the patient's responses to stimuli (Eye response - verbal response - motor response)
Timepoint
Daily from 3 days before surgery to 5 days after
Method of measurement
Glasgow Coma Scale (GCS) Scoring system

3

Description
Check the quality of sleep
Timepoint
Daily from 3 days before surgery to 5 days after
Method of measurement
Epworth Sleep scale questionnaire (ESS)

4

Description
Examining the pain intensity of patients
Timepoint
Daily from 3 days before surgery to 5 days after
Method of measurement
Numeric Rating Scale questionnaire (NRS)

5

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

6

Description
Duration of hospitalization
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

7

Description
Measuring the duration of delirium
Timepoint
From the time people are diagnosed with delirium until the time they recover
Method of measurement
Count the number of days

Intervention groups

1

Description
Intervention group (Drug Group): 1 Oral tablet of Melatonin 10 mg manufactured by Jalinous Iran company will be taken at night from 3 days before surgery and up to 5 days after surgery.
Category
Prevention

2

Description
Control group: 1 Oral Tablet, Ineffective But Similar to the Medicine (Placebo) Manufactured by Jalinous Iran Company will be Taken at Night from 3 Days Before Surgery and up to 5 Days After Surgery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center

Shahid Rajaie hospital
Full name of responsible person
Maryam Daei
Street address
Phase 2, block 9, entrance 1, 11th floor, NO.180, 180th unit, Ekbatan town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Vice President of Research and Technology of Alborz University of Medical Sciences
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Research and Technology Deputy Bldg, 45 meter Golshahr, Shahid Safarian Alley
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3198764653
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Research@abzums.ac.ir
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
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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
It will be explained after the judging.
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