

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 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

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Iran (Islamic Republic of)

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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

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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
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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

Karaj University of Medical Sciences

Full name of responsible person

Maryam Daei

Position

Assistant Professor

Latest degree

Ph.D.

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

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