

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Melatonin on Delirium after Cardiac Surgery

Protocol summary

Study aim

Determining the Effect of Melatonin on Delirium After Cardiac Surgery

Design

Two arm parallel groups randomized trial with blinded postoperative care and outcome assessment

Settings and conduct

After obtaining permission from the Ethics Committee, the patients will be randomized to two groups of 30 (case and control). In the case of malathion, the control group will be given a placebo. Delirium incidence variables (based on CAM-ICU) and severity It (according to MDAS) is reviewed and recorded. Also, information on the duration of the operation, the duration of the cardiopulmonary bypass pump, the length of time required for mechanical ventilation after surgery, and the duration of admission to the ICU are recorded and compared in the two groups.

Participants/Inclusion and exclusion criteria

inclusion criteria: 1-age 30 and above 2. Candidate for elective or semi-elective coronary artery bypass graft surgery (On-Pump CABG) 3. Risk of Anesthesia 1-3 4- Insensitivity to melatonin exclusion criteria: 1-No informed consent 2. Emergency surgery 3. Presence of melatonin inhibition, allergy to the drug or its compounds. 4. Chronic or recent use of melatonin or hypnotic drugs 5. Treated with barbiturates or anti psychotics 6. History of liver or kidney disease or chronic pulmonary disease

Intervention groups

In the case group, a melatonin(Webber Naturals® Canada) dose of 3 mg, the night before the operation (8 nights) and the morning of the day (6 am) and night (8 nights) until 48 hours after the operation In the control group, the placebo (pharmaceutical gypsum) was prescribed the same day before the surgery (8 nights) and the morning of the day (6 am) and every night (8 nights) until 48 hours after the operation.

Main outcome variables

Delirium incidence; Severity of Delirium; Mechanical

ventilation time; Intensive care unit staying

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180909040979N3**

Registration date: **2019-07-30, 1398/05/08**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-30, 1398/05/08**

Update count: **0**

Registration date

2019-07-30, 1398/05/08

Registrant information

Name

MARYAM ZAMANKHANI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3336 4760

Email address

zamankhani.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-20, 1398/03/30

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Melatonin on Delirium after Cardiac Surgery

Public title

Delirium after Cardiac Surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age 30 and older Candidate for elective coronary artery bypass graft under cardiopulmonary pumps Anesthesia class 1-3 Insensitivity to melatonin

Exclusion criteria:

Lack of informed consent Emergency Surgery Chronic or recent use of melatonin or hypnotic drugs Treated with barbiturates or anti psychotics History of liver or kidney disease or chronic pulmonary disease

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization: Individuals are randomly divided into two groups based on randomized block randomization method. Randomized blocks are used for this purpose. A random sample based on this method from Sealedenvelope.com has been extracted.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the intervention group, the melatonin tablet and in the control group a tablet will be given the same shape form. Given the fact that the two tablets do not differ significantly in color and shape, thus it can be said that the patient, surgeon and researcher did not have any information on how the subjects were placed in the group .

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences., Research Deputy., Blvd. Golestan .Ahvaz

City

Ahvaz

Province

Khuzestan

Postal code

15794-61357

Approval date

2019-06-12, 1398/03/22

Ethics committee reference number

IR.AJUMS.REC.1398.199

Health conditions studied

1

Description of health condition studied

Patients candidate for coronary artery bypass graft surgery

ICD-10 code

T82.9

ICD-10 code description

Unspecified complication of cardiac and vascular prosthetic device, implant and graft

Primary outcomes

1

Description

Delirium incidence

Timepoint

From Start of study for 2 days after performing the CABG

Method of measurement

Based on CAM-ICU

2

Description

Severity of delirium

Timepoint

From Start of study for 2 days after performing the CABG

Method of measurement

Based on MDAS

3

Description

Mechanical ventilation duration

Timepoint

6,8,10,12 ,24 hours after surgery

Method of measurement

Hour

4

Description

Duration of ICU staying

Timepoint

2,3,4 days after surgery

Method of measurement

Day

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in group 1 melatonin tablet (Webber Naturals® Canada) (3 mg), the night before surgery (8 nights) and the morning of surgery (6 am) and the night of surgery(8 nights) up to 48 hours after the operation

Category

Prevention

2

Description

Control group: In the placebo group, the same figure tablet was used the night before surgery (8 nights) and the morning of surgery (6 am) and the night of surgery(8 nights) every night (8 nights) until 48 hours after the operation

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Fatemeh Javaherforoosh zadeh

Street address

Golestan hospital.Blvd golestan

City

Ahvaz

Province

Khouzestan

Postal code

15794-61357

Phone

+98 61 3391 9315

Email

f_javaherforoosh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Mohamad Badavi

Street address

Deputy of Research, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

15794-61357

Phone

+98 61 3336 7550

Email

Badavi-m@ajums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Fatemeh Javaherforoosh zadeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

No.1, West Maroon, East13, Kianpars

City

Ahvaz

Province

Khouzestan

Postal code

6155979939

Phone

+98 61 3391 9315

Email

f_javaherforoosh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

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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