Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Khouzestan

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
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
15794-61357

Phone
+98 61 3391 9315

Email
f_javaherforoosh@yahoo.com

Person responsible for updating data

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

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