

# 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

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##### Province

Khouzestan

##### Postal code

6155979939

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##### Email

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Fatemeh Javaherforoosh zadeh

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**Latest degree**

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## Person responsible for updating data

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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