Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 2026

Comparison of dexmedetomidine injection alone or with the addition of oral melatonin on the incidence of delirium after coronary artery bypass graft surgery

Protocol summary

Study aim
Evaluation of the effect of dexmedetomidine supplementation with oral melatonin in the prevention of delirium after coronary artery bypass graft surgery

Design
Randomized Clinical trial with the control group, with parallel groups, double-blind, randomized, phase 3 on 80 patients. Excel software rand function was used for randomization. Simple individual randomization by randomization table

Settings and conduct
Delirium is common after cardiac surgery. This study is performed in Golestan Hospital of Ahvaz as a double-blind randomized study

Participants/Inclusion and exclusion criteria
Inclusion criteria: Candidate for coronary artery bypass graft surgery with cardiopulmonary pump No allergy to melatonin and dexmedetomidine Elective surgery Exclusion criteria: Conscious dissatisfaction Emergency surgery Chronic use of melatonin or hypnotic drugs History of liver or kidney disease or chronic lung disease History of neurological or psychological diseases Ejection Fraction < 30%

Intervention groups
1-Intervention group: In group 1, melatonin at a dose of 3 mg, the night before surgery (9 pm) and the morning of surgery (6 am) and every night (9 pm) for 48 hours after surgery. In the intensive care unit, dexmedetomidine will first receive a bolus of 0.5µg / kg for 20 minutes and then an infusion of -0.7 µg / kg / h for a maximum of 24 hours. 2-Control group: In group 2, placebo tablet, the night before surgery (9 pm) and the morning of surgery (6 am) and every night (9 pm) for 48 hours after surgery. In the intensive care unit, dexmedetomidine will first receive a bolus of 0.5µg / kg for 20 minutes and then an infusion of -0.7 µg / kg / h for a maximum of 24 hours

Main outcome variables
Delirium incidence; Intensity of delirium

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180909040979N7**
Registration date: **2022-05-24, 1401/03/03**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-24, 1401/03/03**
Update count: **0**

Registration date
2022-05-24, 1401/03/03

Registrant information

Name
MARYAM ZAMANKHANI

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
2022-05-22, 1401/03/01

Expected recruitment end date
2022-12-22, 1401/10/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of dexmedetomidine injection alone or with the addition of oral melatonin on the incidence of delirium after coronary artery bypass graft surgery

Public title

The effect of dexmedetomedine and melatonin on delirium

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for coronary artery bypass graft surgery with cardiopulmonary pump No allergy to melatonin and dexmedetomidine Elective surgery Age 40 to 75 years

Exclusion criteria:

Conscious dissatisfaction Emergency surgery Chronic use of melatonin or hypnotic drugs History of liver or kidney disease or chronic lung disease History of neurological or psychological diseases Ejection Fraction < 30%

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is performed on patients candidate for CABG eczema referred to the partner medical centers in the project. The relevant expert divides the patients into two similar groups based on the treatment regimen, age group, sex, severity of the disease, and symptoms, and randomly, using the patient code numbers, one group is group A (dexmedetomidine) and one group is group B (dexmedetomidine+melatonin). For randomization, the permutation block method with six blocks is done using Random allocation software.

Blinding (investigator's opinion)

Double blinded

Blinding description

To blind the study, after the patient enters the study, the doctor prescribes A (dexmedetomidine) or B (dexmedetomidine+melatonin) based on the randomized form. The doctor's prescription is prescribed in the same packages. Clinical caregivers are unaware of the coding assigned to each patient. The person in charge of drug delivery and the patient, the doctor, the person in charge of evaluating the consequences will not know about the codings. The results of the two groups under the headings of groups A and B will be submitted to the statistical analyst.

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

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

City

Ahvaz

Province

Khouzestan

Postal code

1579461357

Approval date

2022-04-19, 1401/01/30

Ethics committee reference number

IR.AJUMS.REC.1401.047

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

First day and second day after extubation

Method of measurement

Based on Confusion Assessment Method for the ICU

2

Description
Severity of delirium
Timepoint
First day and second day after extubation
Method of measurement
Based on Confusion Assessment Method for the ICU

Secondary outcomes

1

Description
Mechanical ventilation duration
Timepoint
6,8,10,12 ,24 hours after surgery
Method of measurement
Hour

2

Description
Duration of ICU staying
Timepoint
2,3,4 days after surgery
Method of measurement
Day

Intervention groups

1

Description
Intervention group: In group 1, melatonin at a dose of 3 mg, the night before surgery (9 pm) and the morning of surgery (6 am) and every night (9 pm) for 48 hours after surgery. In the intensive care unit, dexmedetomidine will first receive a bolus of 0.5µg / kg for 20 minutes and then an infusion of -0.7 µg / kg / h for a maximum of 24 hours
Category
Treatment - Drugs

2

Description
Control group: , In group 2, placebo tablet the night before surgery (9 pm) and the morning of surgery (6 am) and every night (9 pm) for 48 hours after surgery. In the intensive care unit, dexmedetomidine will first receive a bolus of 0.5µg / kg for 20 minutes and then an infusion of -0.7 µg / kg / h for a maximum of 24 hours
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan hospital
Full name of responsible person
Mehrnoosh Zakerkish
Street address
Deputy of Research, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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Other areas of specialty/work
Anesthesiology
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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