

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Country

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 dexmedetomidine 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
 Khuzestan
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

Ahvaz University of Medical Sciences

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

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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