Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

A clinical trial to compare the effectiveness of agomelatine with placebo on rate of delirium in patients admitted to the cardiac surgery intensive care unit

Protocol summary

Study aim

To compare the effectiveness of agomelatine with placebo on rate of delirium in patients admitted to the cardiac surgery intensive care unit

Design

This randomized and double-blind clinical trial with parallel and control groups will be conducted on 74 patients who will be randomly selected using the random number table.

Settings and conduct

Patients admitted to the cardiac surgery intensive care unit to Imam Reza Hospital, Mashhad, Iran are chosen as the participants of the study. In this double-blind study, sealed opaque envelopes will be used to conceal the sequencing. Intervention group will receive the agomelatine and control will receive placebo. The participants and person responsible for data collection are blind to group allocation and the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged between 18 and 75 years; Staying more than 72 hours in the intensive care unit; receiving medication following admission to hospital from the first day; having stable hemodynamics based on confusion assessment method for the ICU (CAM-ICU). Exclusion criteria: Patients who were treated with agomelatine before ICU admission; having agomelatine allergies; pregnant and breastfeeding women; having Alzheimer; having hepatic dysfunction; having high APACHE II score; the patient dies in the first 3 days of admission; patients who require of only parenteral nutrition; using strong 1A2 inhibitors (ciprofloxacin, fluvoxamine).

Intervention groups

The intervention group will receive 25 mg agomelatine orally 18 hours after hospitalization. The control group will receive placebo orally 18 hours after hospitalization.

Main outcome variables

Evaluation and comparison of incidence and severity of delirium, sleep quality, pain management, duration of hospital and intensive care unit stay, duration of mechanical ventilation and mortality rate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220508054780N4**
Registration date: **2024-01-21, 1402/11/01**
Registration timing: **prospective**

Last update: **2024-01-21, 1402/11/01**
Update count: **0**

Registration date

2024-01-21, 1402/11/01

Registrant information

Name

Benyamin Fazli

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3802 2711

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fazlib@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2025-02-19, 1403/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effectiveness of agomelatine with placebo on rate of delirium in patients admitted to the cardiac surgery intensive care unit

Public title

The effectiveness of agomelatine on rate of delirium

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged between 18 and 75 years Staying more than 72 hours in the intensive care unit Receiving medication following admission to hospital from the first day Having stable hemodynamics based on confusion assessment method for the ICU (CAM-ICU)

Exclusion criteria:

Patients who were treated with agomelatine before ICU admission Having agomelatine allergies Pregnant and breastfeeding women Having Alzheimer Having hepatic dysfunction Having high APACHE II score The patient dies in the first 3 days of admission Patients who require of only parenteral nutrition Using strong 1A2 inhibitors (ciprofloxacin, fluvoxamine)

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be simple randomly assigned to two groups using a random table type and opaque envelopes will be used for concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients admitted to the cardiac surgery intensive care unit to Imam Reza Hospital, Mashhad, Iran are chosen as the participants of the study. In this double-blind study, sealed opaque envelopes will be used to conceal the sequencing. Intervention group will receive the agomelatine and control will receive placebo. The participants and person responsible for data collection are blind to group allocation and the type of treatment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Imam Reza Hospital Educational, Research and Treatment Center, Ethics Committee of Mashhad Universit

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

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Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Approval date

2023-07-24, 1402/05/02

Ethics committee reference number

IR.MUMS.IRH.REC.1402.110

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05

ICD-10 code description

Delirium not superimposed on dementia, so described

Primary outcomes

1

Description

Incidence and severity of delirium

Timepoint

Before the intervention and twice a day until the end of the intervention

Method of measurement

Based on Confusion Assessment Method for the ICU (CAM-ICU)

2

Description

Sleep quality

Timepoint

Before the intervention and twice a day until the end of the intervention

Method of measurement
Based on Pittsburgh Sleep Quality Index (PSQI)

3

Description
Pain management
Timepoint
Before the intervention and twice a day until the end of the intervention
Method of measurement
Based on Critical-care pain observation tool (CPOT)

Secondary outcomes

1

Description
Duration of hospital care unit stays
Timepoint
After intervention
Method of measurement
Based on the number of days of hospitalization

2

Description
Number of days dependent on ventilator
Timepoint
After intervention
Method of measurement
The number of days the ventilator is used for the patient

3

Description
Mortality rate
Timepoint
After intervention
Method of measurement
Based on acute physiology and chronic health evaluation score (APACHE) II score

Intervention groups

1

Description
Intervention group: The intervention group will receive 25 mg agomelatine (Tadbir Kalaye Jam, Tehran, Iran) orally 18 hours after hospitalization. This will be administered daily for a minimum of 3 days and a maximum of 14 days, in addition to their prescribed medications.
Category
Treatment - Drugs

2

Description
Control group: The control group will receive placebo (It has the same color, taste, structure and shape as agomelatine, produced by the research center of faculty of pharmacy, Mashhad University of Medical Sciences) orally 18 hours after hospitalization. This will be administered daily for a minimum of 3 days and a maximum of 14 days, in addition to their prescribed medications.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Benyamin Fazli
Street address
Imam Reza Hospital, Imam Reza Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Benyamin Fazli

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Anesthesiology department. Mashhad University of medical sciences , University ave .,Mashhad, Razavi Khorasan Province, Iran

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Person responsible for scientific inquiries

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Full name of responsible person
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The research data obtained from the main outcomes of the study can be shared freely as 'open data'.

When the data will become available and for how long
6 months after publishing the results

To whom data/document is available
The research data is exclusively accessible to the researchers working at universities and centers for scientific research.

Under which criteria data/document could be used
The research data is exclusively accessible to the researchers working at universities and centers for

scientific research.

From where data/document is obtainable

Benyamin Fazli provides the data analysis to the applicants via email: fazlib@mums.ac.ir

What processes are involved for a request to access data/document

Applicants can send emails to him and receive a response within a week.

Comments