Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of haloperidol versus dexmedetomidine in the prevention of delirium after cardiac surgery

Protocol summary

Study aim

Comparison of haloperidol and dexmedetomidine in the prevention of delirium after cardiac surgery using cardiopulmonary bypass

Design

A double-blind clinical trial, two parallel groups, randomized, phase 3 on 180 patients in two groups of 90 people, which will be used for randomization using randlist online software, and informed written consent will be obtained from all patients.

Settings and conduct

In Madani Heart Hospital in Tabriz, 180 patients will be randomly assigned to one of the two groups of 90 people, haloperidol or dexmedetomidine. Postoperatively, when the patients are admitted to the ICU, the loading dose injection and then the haloperidol or dexmedetomidine infusion will start and continue for 12 hours. During hospitalization in the ICU, the incidence of delirium in the two monitoring groups will be recorded and compared with the CAM-ICU tool.

Participants/Inclusion and exclusion criteria

Inclusion criteria: adult patients aged 18 to 75 who are candidates for elective cardiac surgery with cardiopulmonary bypass Exclusion criteria: history of previous stroke without complete recovery for 5 years, emergency surgery, death in ICU, patients under 18 years old and over 75 years old, history of neurological and mental diseases or taking antipsychotic drugs, not using bi Cardiopulmonary, allergy to haloperidol or dexmedetomidine, dementia, QTc interval more than 500 milliseconds or complete heart block, history of malignant neuroleptic syndrome, bradycardia and liver and kidney diseases.

Intervention groups

Haloperidol group: As soon as the patient is admitted to the ICU, the loading dose injection and then the haloperidol drug infusion will be start. Dexmedetomidine group: As soon as the patient is admitted to the ICU, the loading dose injection and then the dexmedetomidine drug infusion will be start.

Main outcome variables

Occurrence of delirium during hospitalization in ICU

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080830001127N9**
Registration date: **2022-12-04, 1401/09/13**
Registration timing: **prospective**

Last update: **2022-12-04, 1401/09/13**
Update count: **0**

Registration date

2022-12-04, 1401/09/13

Registrant information

Name

Eissa Bilehjani

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 3329 6124

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of haloperidol versus dexmedetomidine in the prevention of delirium after cardiac surgery

Public title
Comparison of the effect of haloperidol versus dexmedetomidine in the prevention of delirium after cardiac surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
All adult patients 18 up to 75 years old , candidates of elective cardiac surgery with cardiopulmonary bypass
Exclusion criteria:
History of previous CVA without full recovery for 5 years - emergency procedures - death in ICU Emergency surgeries Death in ICU Patients under 18 years old and over 75 years old History of neurological and mental diseases or taking antipsychotic drugs Not using cardiopulmonary bypass Allergy to haloperidol or dexmedetomidine Dementia QTc interval greater than 500 ms or complete heart block History of malignant neuroleptic syndrome Bradycardia Liver and kidney diseases
Age
From **18 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: **180**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done by random distribution in blocks of 9 based by on line software (www.randomlists.com).
Blinding (investigator's opinion)
Double blinded
Blinding description
Anesthesiologists who are responsible for managing the patient during and after the operation, diagnosing delirium and collecting data will administer the drug under investigation through coded syringes, the drug will be prepared by a nurse colleague. All these specialists will be unaware of the type of drug injected to the patient. The nurse's colleague will not have any role in the process of patient management, data collection and variables examined in the patient. The patient will also be unaware of the type of injected medicine.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of tabriz University of Medical Sciences
Street address
Vice chancellor for research, Golgasht street
City
tabriz
Province
East Azarbaijan
Postal code
5183915881
Approval date
2022-06-01, 1401/03/11
Ethics committee reference number
IR.TBZMED.rec.1401.190

Health conditions studied

1

Description of health condition studied
Delirium
ICD-10 code
f05
ICD-10 code description
Other delirium

Primary outcomes

1

Description
Delirium
Timepoint
during ICU stay
Method of measurement
CAM–ICU measurement tool

Secondary outcomes

1

Description
Duration of need to mechanical ventilation

Timepoint
During hospitalization in ICU
Method of measurement
Counting the number of hours of mechanical ventilation in the ICU

2

Description
Length of stay in ICU
Timepoint
Reviewing the patient ICU records
Method of measurement
Counting the number of days of ICU stay

3

Description
Mortality
Timepoint
During hospitalization in ICU
Method of measurement
Reviewing the patient ICU records

Intervention groups

1

Description
Intervention group: As soon as the patient is admitted to the ICU, the loading dose and then the infusion of dexmedetomidine will be started.
Category
Prevention

2

Description
Intervention group: As soon as the patient is admitted to the ICU, the loading dose and then the infusion of haloperidol will be started.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Shahid Madani Heart Hospital
Full name of responsible person
Eissa Bilehjani
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Shahid Madani Heart Hospital, Daneshghah street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Gholamreza Farid Alaei
Street address
Research and technology deputy, third floor, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht street, Tabriz
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Eissa Bilehjani
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work

Cardiovascular anesthesia
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Data will not be shared publicly.
When the data will become available and for how long
The data will be available 6 months after the results are published.
To whom data/document is available
The data will be available to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
No special conditions are defined.
From where data/document is obtainable
ryousefiasl@gmail.com
What processes are involved for a request to access data/document
متقاضی با ذکر علت تقاضا با ایمیل ذکر شده ارتباط برقرار کند.
Comments