

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 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)

Phone

+98 41 3329 6124

Email address

bilehjanii@tbzmed.ac.ir

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

Street address

Shahid Madani Heart Hospital, Daneshghah street

City

Tabriz

Province

East Azarbaijan

Postal code

5166615573

Phone

+98 41 3337 3950

Fax

+98 41 3337 3950

Email

isadavod@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

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

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Phone

+98 41 3335 7310

Fax

+98 41 3335 7310

Email

research-vice@tbzmed.ac.ir

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

Street address

Madani Heart Center, Daneshgah Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166615573

Phone

+98 41 3337 3950

Fax

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Email

isasdavod@gmail.com

Person responsible for scientific inquiries

Contact

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Tabriz University of Medical Sciences

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Person responsible for updating data

Contact

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Tabriz University of Medical Sciences

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Email

bilehjani@tbzmed.ac.ir

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