Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of haloperidol and placebo in the prevention of delirium after heart surgery

Protocol summary

Study aim
Prevention of delirium by taking Haloperidol after cardiac surgery

Design
A total of 180 patients will be selected based on the studies and statistical calculations that meet the inclusion criteria and then assigned to the intervention and control groups by binary blocking (block randomization with blocks of size 2). In the intervention group, Haloperidol and in the control group Distilled water (as placebo) will be used .The study is a randomized, double-blind, placebo-controlled clinical trial.

Settings and conduct
One hundred and eighty (180) patients candidates for heart surgery who visit the operating room of Shahid Madani Hospital in Tabriz will participate in this study. Both Haloperidol and distilled water will be administered by the researcher and with the number needed every morning before surgery begins. There will be two types of envelopes. Envelope A contains a syringe containing Haloperidol and envelope B contains distilled water. Each patient will receive these envelopes on the basis of an A or B code by an anesthetist who is unaware of the type of drug. In this study, the patient and the anesthetist will be blinded to the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All adult patients between the ages of 18 and 75 and candidates for elective cardiac surgery. Exclusion criteria: History of neurological diseases; Allergy to haloperidol; A history of stroke; Previous use of anti-psychotic drugs.

Intervention groups
Intervention group: In this group,haloperidol with a concentration of 0.5 mg / cc will be injected immediately after the onset of pulmonary heart bypass (CPB). Control group: In this group, only distilled water (as a placebo) will be prescribed with the specifications of the drugs of the intervention group.

Main outcome variables
The incidence of delirium, the severity of delirium, blood pressure and laboratory variables (sodium and potassium and ABG variables).

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20080830001127N8**
Registration date: **2020-04-18, 1399/01/30**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-18, 1399/01/30**
Update count: **0**

Registration date
2020-04-18, 1399/01/30

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
2020-02-20, 1398/12/01
Expected recruitment end date
2020-08-22, 1399/06/01
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of haloperidol and placebo in the prevention of delirium after heart surgery

Public title

Haloperidol effect on postoperative delirium prophylaxis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All adult patients between the ages of 18 and 75 years old and candidates for elective cardiac surgery

Exclusion criteria:

History of neurological diseases Allergy to haloperidol Parkinson's disease A history of stroke Emergency surgery Previous use of anti-psychotic drugs

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients wishing to participate in the study who meet the inclusion criteria will be selected through convenient sampling and then randomly assigned to two control and intervention groups using Randlist software and blocks of size two.

Blinding (investigator's opinion)

Double blinded

Blinding description

The anesthesiologist who is responsible for the patients management of anesthesia will administer the medicine(s) via coded syringes had been prepared previously and will not be aware of the injected drug, and anesthesia nurse who is responsible for collection of patients information and study variables and is unaware of the administered drug will record the check- list during surgery and in the recovery.Also the patient is unaware of the injected medicine.

Placebo

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

2020-02-01, 1398/11/12

Ethics committee reference number

IR.TBZMED.REC.1398.1173

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05.8

ICD-10 code description

Other delirium

Primary outcomes

1

Description

Delirium

Timepoint

Before entering the ICU, before the pump, during the pump, after the pump, the first day of the ICU, the second day of the ICU, the third day

Method of measurement

Using the Richmond Agitation-Sedation Scale criterion

2

Description

Intensity of delirium

Timepoint

Before entering the ICU, before the pump, during the pump, after the pump, the first day of the ICU, the second day of the ICU, the third day

Method of measurement

Using CAM-ICU confusion recognition and review tools

3

Description
Blood pressure
Timepoint
Before entering the ICU, before the pump, during the pump, after the pump, the first day of the ICU, the second day of the ICU, the third day
Method of measurement
Using a mercury barometer

4

Description
Laboratory variables (sodium)
Timepoint
Before entering the ICU, before the pump, during the pump, after the pump, the first day of the ICU, the second day of the ICU, the third day of the ICU
Method of measurement
By taking blood and determining laboratory values

5

Description
Laboratory variables(potassium)
Timepoint
Before entering the ICU, before the pump, during the pump, after the pump, the first day of the ICU, the second day of the ICU, the third day of the ICU
Method of measurement
By taking blood and determining laboratory values

6

Description
Arterial blood gas (ABG)
Timepoint
Before entering the ICU, before the pump, during the pump, after the pump, the first day of the ICU, the second day of the ICU, the third day of the ICU
Method of measurement
By taking blood and determining laboratory values

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, haloperidol (HALODIC, ampoule of 5 mg per 1 ml, produced by Caspian company) with a concentration of 0.5 mg / cc will be injected immediately after the onset of pulmonary heart bypass (CPB).
Category
Treatment - Drugs

2

Description
Control group: In this group, only distilled water (as a placebo) will be prescribed with the same characteristics of the drugs used in the intervention group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Madani hospital
Full name of responsible person
Eissa Bilehjani
Street address
Madani Heart Center, Daneshgah Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166615573
Phone
+98 41 3337 3950
Fax
+98 41 3337 3950
Email
bilehjanii@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Abolghasem Jouyban
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
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Madani Heart Center, Daneshgah street, Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166615573

Phone
+98 41 3337 3950

Fax
+98 41 3337 3950

Email
bilehjanii@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Eissa Bilehjani

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Madani Heart Center, Daneshgah street, Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166615573

Phone
+98 41 3337 3950

Fax
+98 41 3337 3950

Email
bilehjanii@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Eissa Bilehjani

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Madani Heart Center, Daneshgah street, Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166615573

Phone
+98 41 3337 3950

Fax
+98 41 3337 3950

Email
bilehjanii@tbzmed.ac.ir

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

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
A portion of the data that represents the final outcome

When the data will become available and for how long
starting 6 months after publication

To whom data/document is available
All Physicians and residents of the department of Anesthesia

Under which criteria data/document could be used

There will be no specific limitations to the utilization of the data.

From where data/document is obtainable

Dr .Eissa Bilehjani,Madani Heart Center, Daneshgah Street, Tabriz, Tn Phone+98 41 33373950 Fax+98 41 33373950 bilehjanii@tbzmed.ac.ir

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

Be approved by the Research Vice-President at first

Comments