

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Impact of Vitamin C Supplementation on Post-Cardiac Surgery delirium

Protocol summary

Study aim

The incidence of delirium with vitamin C judging after heart 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. In the intervention group, Vitamin C 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

Patients will be randomly divided into two groups according to the random number table. Both Vitamin C and Distilled water will be administered by the planter and with the number needed every morning before surgery begins. There will be two types of envelopes. Envelope A contains a syringe containing Vitamin C 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 ages of 18 and 75 and candidates for elective cardiac surgery.
Exclusion criteria: Previous use of anti-psychotic drugs. Surgeries that does not use a heart or lung pump
Previous use of anti-psychotic drugs. Patients with mental retardation.

Intervention groups

Intervention group: In this group, 2 grams of vitamin C (vitamin C, 5 ml injection solution of 100 mg / 1 ml, distributed by daroo pakhsh drug factories) will be injected immediately after the start 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: **IRCT20080830001127N7**

Registration date: **2020-04-17, 1399/01/29**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-17, 1399/01/29**

Update count: **0**

Registration date

2020-04-17, 1399/01/29

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
Impact of Vitamin C Supplementation on Post-Cardiac Surgery delirium

Public title
Impact of Vitamin C Supplementation on delirium

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
All adult patients between the ages of 18 and 75 and candidates for elective cardiac surgery
Exclusion criteria:
Previous use of anti-psychotic drugs Surgeries that does not use a heart or lung pump Previous use of anti-psychotic drugs Patients who are not extubated until 5 days after surgery Patients with mental retardation

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **180**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study we use balanced randomization that at first four blocks with 9 combination will be formed and blocks will be numbered from 1to9. Compared to the simple randomization method, in this method the size of equilibrium of intervention and placebo groups will be established both during and at the end of study(randomization method is pre and post accidental blocks and will be done by randlist software)

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

Ethic 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

2019-12-22, 1398/10/01

Ethics committee reference number

IR.TBZMED.REC.1398.1017

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05.8

ICD-10 code description

Other delirium Delirium of mixed origin Postoperative 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 and potassium and ABG variables)

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, 2 grams of vitamin C (vitamin C, 5 ml injection solution of 100 mg / 1 ml, distributed by daroo pakhsh drug factories) will be injected immediately after the start 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 specifications of the drugs of 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 innovation 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