# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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
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**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
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**Email**
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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**
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**