Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The neuroprotective effect of memantine during cardiopulmonary bypass in patients that are candidate for cardiac surgery

Protocol summary

Study aim
Evaluating the nueroprotective effect of memantine during cardiopulmonary bypass

Design
In this interventional study, we will investigate the release of S100B Protein with the consent of patients and explanations about the process of the drug prescribing. Patients will be divided into two groups. The control group will not receive placebo. The second group will receive memantine at a dose of 10 mg / bid within 3 days before surgery. The first blood sample will be taken from the patient before surgery, and the next samples will be taken after cardiopulmonary bypass (CPB) weaning, 6 hours and 24 hours post-operatively to measure plasma S100B.

Settings and conduct
This study will be conducted in Mazandaran Heart Center. Prescribing of the memantine will be done in the preoperative period and the samples will be sent to the laboratory at the appointed time. Blinding will be performed for the surgeon and laboratory staff, and the patient will be followed up to evaluate the tests through the file number.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients that are candidate for open heart surgery Age between 18 to 80 years Exclusion criteria: Acute or chronic renal or hepatic failure History of memantine consumption within last 6 months History of neurological disorders

Intervention groups
Intervention group: memantine 10 mg/bid for 3 days before surgery Control group: will not receive any medication or placebo

Main outcome variables
S100B levels Occurrence of neurological deficit after surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200502047276N1**
Registration date: **2020-06-02, 1399/03/13**
Registration timing: **prospective**

Last update: **2020-06-02, 1399/03/13**
Update count: **0**

Registration date
2020-06-02, 1399/03/13

Registrant information

Name
Alireza Sanei Motlagh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3331 4755

Email address
alireza.scts@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-21, 1399/04/01

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

The neuroprotective effect of memantine during cardiopulmonary bypass in patients that are candidate for cardiac surgery

Public title
The neuroprotective effect of memantine during cardiopulmonary bypass
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients that are candidate for open heart surgery Age between 18 to 80 years
Exclusion criteria:
Acute or chronic renal failure (AKI stage 4 or 5) Creatinine clearance less than 30 ml/min Moderate to severe hepatic failure Autoimmune disease Alzheimer or dementia History of memantine consumption within last 6 months History of seizure, CVA, or psychiatric disorders
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **4**
preoperative - post cardiopulmonary bypass - 6 hours post-operative - 24 hours post-operative
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences
Street address
Artesh Blvd, Mazandaran heart center, Mazandaran University of Medical Sciences, Sari, Iran
City
Sari
Province
Mazandaran
Postal code
48471-91971
Approval date
2019-05-29, 1398/03/08
Ethics committee reference number
IR.MAZUMS.REC.1398.333

Health conditions studied

1

Description of health condition studied
Ischemic heart diseases
ICD-10 code
I25
ICD-10 code description
Chronic ischemic heart disease

Primary outcomes

1

Description
S100B protein level during preoperative and postoperative courses
Timepoint
before surgery, after cardiopulmonary bypass weaning, 6 hours after surgery, 24 hours after surgery
Method of measurement
Enzyme linked immunoassay (ELISA), Human Protein S100-B(S100B)ELISA Kit

Secondary outcomes

1

Description
Neurological deficits
Timepoint
Post-operation up to 30 days
Method of measurement
Neurological examination

Intervention groups

1

Description
Intervention group: patients that received memantine 10 mg/bid for 3 days before surgery
Category
Treatment - Drugs

2

Description
Control group: will not receive any medication or placebo
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Mazandaran heart center
Full name of responsible person
Shervin Ziabakhsh Tabary
Street address
Artesh Blvd, Mazandaran University of Medical Sciences, Sari, Iran
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Sari
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48471--91971
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shervin.zia@gmail.com
Web page address
https://www.ctsnet.org/home/stabary

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Deputy of research and technology - Cardiovascular Research Center
Street address
Artesh Blvd, Mazandaran Heart Center, Sari, Iran
City
Sari
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Postal code
48471-91971
Phone
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Email
shervin.zia@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Alireza Sanei Motlagh
Position
Medical doctor
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
Street address
Artesh Blvd. Mazandaran Heart center, Mazandaran University of medical sciences, Sari, Iran
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Person responsible for updating data

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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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Demographic data, laboratory results and outcomes

When the data will become available and for how long
accessible immediately after printing the results

To whom data/document is available
For all medical researchers and physicians

Under which criteria data/document could be used
Necessary conditions for submitting an application are subject to having an academic degree in medical sciences or studying in medical sciences

From where data/document is obtainable
via email: shervin.zia@gmail.com
alireza.scts@yahoo.com

What processes are involved for a request to access data/document
After authentication, the information will be sent within 4 weeks.

Comments