

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

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

Protocol summary

Study aim

Evaluating the neuroprotective 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

City

Sari

Province

Mazandaran

Postal code

48471--91971

Phone

+98 11 3331 4755

Email

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

Province

Mazandaran

Postal code

48471-91971

Phone

+98 11 3331 4755

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

City

Sari

Province

Mazandaran

Postal code

48471-91971

Phone

+98 11 3331 4755

Fax

Email

alireza.scts@yahoo.com

Person responsible for scientific 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

City

Sari

Province

Mazandaran

Postal code

48471-91971

Phone

+98 11 3331 4755

Fax

Email

alireza.scts@yahoo.com

Person responsible for updating data

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

City

Sari

Province

Mazandaran

Postal code

48471-91971

Phone

+98 11 3331 4755

Fax**Email**

alireza.scts@yahoo.com

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