

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation of using cerebral oximetry in decreasion of mental status disorder in patient undergoing cardiac surgery requiring extracorporeal circulation . by using mini menal status examination in pre and post operaion.

Protocol summary

Study aim

Prevention of cognitive disorders using cerebral oximetry in patients undergoing heart surgery requiring extracorporeal circulation

Design

A concealed, randomized, three way blinded, controlled clinical trial with a parallel group design of 100 patients. For randomization, the method of random allocation law and the website www.randomization.com are used, and for allocation concealment, sealed envelopes are used.

Settings and conduct

After selection and obtaining consent from the participant, randomization and concealment are done. There are 100 participants in total, and there are equal numbers in two intervention and control groups. Subjects will be tested for mental function before the operation and eight days after the operation. Cerebral oximetry is used in the intervention group and not used in the control group. The study is three-way blind: the participant does not know which group he is in, the researcher does not know which group the person being tested is in, the evaluators are analyzing the test results and does not know which group they are in .

Participants/Inclusion and exclusion criteria

A candidate for heart surgery requiring extracorporeal circulation, age under 65 and No carotid stenosis. Not having, kidney failure, history of mental disorders, addiction and drug use, head trauma and cerebrovascular accidents. Being literate in reading and writing.

Intervention groups

In the intervention group, during extracorporeal blood circulation, cerebral oximetry is used, and by using this tool, changes in blood pressure and blood gases are also applied according to the result of cerebral oximetry. In

the control group, cerebral oximetry is not used and changes in blood pressure and blood gases are adjusted according to standard values.

Main outcome variables

Mental disorder after heart surgery requiring extracorporeal circulation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220427054671N1**

Registration date: **2022-07-11, 1401/04/20**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-11, 1401/04/20**

Update count: **0**

Registration date

2022-07-11, 1401/04/20

Registrant information

Name

Morteza Mazaher hesari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7650 4028

Email address

mhmori124@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-09, 1401/04/18
Expected recruitment end date
 2022-08-15, 1401/05/24
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Evaluation of using cerebral oximetry in decrease of mental status disorder in patient undergoing cardiac surgery requiring extracorporeal circulation . by using mini mental status examination in pre and post operation.

Public title
 Evaluation of using cerebral oximetry in decrease of brain disorder in patient undergoing on pump cardiac surgery

Purpose
 Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 patient whom candidate for cardiac surgery requiring extra corporeal circulation . less than 65 years old
 absence of carotid stenosis in patients over 60 years old.
 not having a history of benzodiazepines and opium addiction before the operation . not having a history of mental disorders . no history of kidney disorder and anemia and history of blood transfusion . not having a history of trauma and cerebrovascular accidents, including stroke . having literate in reading and writing .
Exclusion criteria:

Age
 From **18 years** old to **65 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
 Target sample size: **100**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Allocation law method Randomization is the simplest method of limited randomization. This method represents a large block for the entire sample volume. This means that the balance in the number of people assigned to each group will be achieved at the end of the study. For this purpose, first a volume Determined the overall sample and then randomly assigned a group of them to group A and the rest to group B. For example, in a study with a sample size of 100 people, 50 balls for the intervention group A and 50 balls for the intervention group B inside a lottery container then the balls are randomly removed from the container without

replacement and the created sequence is recorded .
 allocation concealment method: using non-transparent sealed envelopes with random sequence

Blinding (investigator's opinion)
 Triple blinded

Blinding description
 Blinding of the participants: After explaining the study and obtaining consent from the patient to participate in the study, he does not know which group he will be placed in. Blinding of the researcher: the researcher does not know which group the participant is in during the test before and after the operation. Blinding of the outcome assessor: the person who evaluates the occurrence or non-occurrence of the outcome does not know which group the information belongs to during the evaluation.

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Mashhad University of Medical Sciences
Street address
 No.11 , sh madani Ave.,Moradbak Alley., narmak
City
 Tehran
Province
 Tehran
Postal code
 1643665341

Approval date
 2022-02-15, 1400/11/26

Ethics committee reference number
 IR.MUMS.MEDICAL.REC.1400.785

Health conditions studied

1

Description of health condition studied
 Post cardiac operation cognitive disorders

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
 Mini mental status test score

Timepoint

The day before the operation and at the time of discharge from the hospital or eight days after the operation

Method of measurement

Mini mental status test

Secondary outcomes

1

Description

NO

Timepoint

NO

Method of measurement

NO

Intervention groups

1

Description

Intervention group: In the intervention group, during extracorporeal blood circulation, cerebral oximetry is used, and by using this tool, changes in blood pressure and blood gases are also applied according to the result of cerebral oximetry. Control group: Cerebral oximetry is not used in the control group and changes in blood pressure and blood gases are adjusted according to standard values

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Imam reza hospital

Full name of responsible person

Nahid Zirak

Street address

Imam reza hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

zirakn@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour

Street address

Medical university, Daneshgah Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3843 0249

Email

GhayourM@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mazaher Hesari Morteza

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Others

Street address

No11, madani Ave, Moradbak Alley, narmak

City

Tehran

Province

Tehran

Postal code

1643665341

Phone

+98 21 7728 8396

Email

mhmori124@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Morteza Mazaher hesari

Position

Student

Latest degree

Master

Other areas of specialty/work

Cardiology

Street address

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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

No - There is not a plan to make this available

Title and more details about the data/document

The main result of the study and the changes observed in the parameters being measured in the intervention group and the answer to the main question of the study

When the data will become available and for how long

Beginning of the access period 07/01/1401

To whom data/document is available

Data access is possible for researchers working in academic and practical institutions in the field of medicine.

Under which criteria data/document could be used

The request for statistical and psychological analysis is accepted by people who are active in this field, and people who are active in the field of heart surgery and a request for improvement in obtaining the result that is possible with further investigation and broader analysis of the data can also have access to the data.

From where data/document is obtainable

Morteza Mazaher hesari cell: 00989904944866

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

First, contact the person who registers and conducts the study, and after explaining the reason for the need for data and documentation and consulting with the supervisor, the information will be provided.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Morteza Mazaher hesari

Position

Student

Latest degree

Master

Other areas of specialty/work

Cardiology

Street address

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