

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Clinical trial comparing post cardiac surgery neurological side effects in interventional group for maintain regional cerebral O2 saturation more than 50% versus non interventional group

Protocol summary

Study aim

modify oxygenation of the brain during cardiac surgery for prevention of post operative neurological side effects.

Design

This prospective, randomized study will be composed of 200 consecutive patients who underwent a cardiac surgery with cardio pulmonary bypass(CPB) pump. patients are randomly assigned to two groups using random numbers table . monitoring of Cerebral oximetry (rScO2) will be performed on case group and others (control group) without any monitoring of cerebral oxygenation. If the absolute threshold rScO2 <50%, interventions to maintain regional rScO2 at, or above, the baseline value will be performed. For the control group, rScO2 will not be recorded and no specific treatments will be employed.

Settings and conduct

This prospective, randomized study will be composed of 200 consecutive patients who underwent a cardiac surgery with cardio pulmonary bypass(CPB) pump. Ethics committee approval will be received along with the informed consent of each patient. patients are randomly assigned to two groups using random numbers table .monitoring of Cerebral oximetry (rScO2) will be performed on case group and others (control group) without any monitoring of cerebral oxygenation. If the absolute threshold rScO2 <50%, interventions to maintain regional rScO2 at, or above, the baseline value will be performed including increasing Paco2 to 45mmHg, increasing blood pressure by increasing blood flow pump, use of inotropes, lower oxygen consumption of the brain using barbiturates and repositioning the patient's head. percentile of desaturation below 50% and seconds of desaturation were recorded. For the control group, rScO2 will not be recorded and no specific treatments will be employed. any neurological side effects such as hallucinations, delirium, stroke and so on

up to three days after surgery will be recorded. length of stay in ICU will be recorded.

Participants/Inclusion and exclusion criteria

This study will be composed of 200 consecutive patients who underwent a cardiac surgery with CPB pump. Patients with history of psychological disorder as well as patients who were taking psychiatric drugs will be excluded. All of the participants will be elective subjects; emergent cases will not be included.

Intervention groups

monitoring of Cerebral oximetry (rScO2) will be performed on case group and others (control group) without any monitoring of cerebral oxygenation. If the absolute threshold rScO2 <50%, interventions to maintain regional rScO2 at, or above, the baseline value will be performed including increasing Paco2 to 45mmHg, increasing blood pressure by increasing blood flow pump, use of inotropes, lower oxygen consumption of the brain using barbiturates and repositioning the patient's head.

Main outcome variables

any neurological side effects such as hallucinations, delirium, stroke and so on up to three days after surgery will be recorded.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161022030421N2**

Registration date: **2018-03-02, 1396/12/11**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-02, 1396/12/11**

Update count: **0**

Registration date

2018-03-02, 1396/12/11

Registrant information

Name

Marzieh Lak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2244 9013

Email address

marziehlak@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-23, 1396/10/02

Expected recruitment end date

2018-05-23, 1397/03/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparing post cardiac surgery neurological side effects in interventional group for maintain regional cerebral O2 saturation more than 50% versus non interventional group

Public title

comparing post cardiac surgery neurological side effects in interventional group for maintain regional cerebral O2 saturation more than 50% versus non interventional group

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

patients who underwent a cardiac surgery with cardiopulmonary bypass pump (CPB pump).

Exclusion criteria:

Patients with history of psychological disorder patients who were taking psychiatric drugs

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 200

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was stratified using a random table number

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 baqiyatallah university of medical sciences

Street address

Baqiyatallah university of medical science, Mollasadra Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1435915371

Approval date

2017-12-17, 1396/09/26

Ethics committee reference number

IR.BMSU.REC.1395.399

Health conditions studied

1

Description of health condition studied

neurological side effects after cardiac surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

neurological side effects

Timepoint

Up to 72 hours after surgery

Method of measurement

Interview and neurological examination

Secondary outcomes

empty

Intervention groups

1

Description

Interventional group: A group that monitoring of Cerebral oximetry (rScO₂) will be performed .interventions were performed to maintain rScO₂ at, or above the baseline value, including increased Paco₂ to 45 mmHg, increases blood pressure by increasing blood flow pump, use of inotropes, lower oxygen consumption of the brain using barbiturates and re positioning the patient's head.

Category

Prevention

2

Description

Control group: A group that is routinely monitored and there is no intervention for them

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah hospital

Full name of responsible person

Marzieh Lak

Street address

Baqiyatallah University of Medical Science, Mollasadra Street, Sheikh Bahaee Street, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Mohammad Hasan Kalantar

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k-motamedi@hotmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Marzieh Lak

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

all collected deidentified IPD

When the data will become available and for how long

starting 1 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

for meta analysis

From where data/document is obtainable

from Email

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

By sending a request to the university Vice-Dean for Research and obtaining a license

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Marzieh Lak

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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