Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
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Iran (Islamic Republic of)
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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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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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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
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