Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 2026

The study of the effect of the use of Epinephrine, Norepinephrine and Phenylephrine drugs during cardiopulmonary bypass on brain oxygenation in patients undergoing open heart surgery

Protocol summary

Study aim
The study of the effect of the use of Npinephrine, Norepinephrine and Phenylephrine drugs during cardiopulmonary bypass on brain oxygenation in patients undergoing open heart surgery

Design
90 participans for open heart surgery candidates are randomly divided to three groups. The clinical trial will consist of three parallel and two-blind groups.

Settings and conduct
This study will be conducted in the operating room and ICU at Shahid Rajaee Heart Center and patients will be unaware of the type of medication used.

Participants/Inclusion and exclusion criteria
Inclusion criterria: Patient satisfaction to participate in the study, patients undergoing elective open-heart surgery, patients over 18 years of age, no history of transient cerebral ischemic disease or stroke, lack of stenosis of the carotid arteries of more than 70%, or no clear stenosis, No previous history of previous cardiac surgery, no diabetes mellitus (with the opinion of an internal medicine specialist), and uncontrolled blood pressure (with the opinion of the cardiologist). Exclusion criteria: cardiac arrest before starting of by-pass, no need to prescribe inotropic drugs during Pulmonary artery bypass surgery

Intervention groups
Based on the random categorization of patients in the three groups under the interventionduring the bypass to maintain blood pressure in patients above 60 mmHg after increasing the flow, if necessary,Norepinephrine drugs of 5 to 10 micrograms and Epinephrine 5 to 10 micrograms and Phenylefrin 40 to 60 micrograms will be used.

Main outcome variables
Brain oxygen saturation and arterial blood gases and hemoglobin and hematocrit will be recorded.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190514043582N1**
Registration date: **2019-06-18, 1398/03/28**
Registration timing: **prospective**

Last update: **2019-06-18, 1398/03/28**
Update count: **0**

Registration date
2019-06-18, 1398/03/28

Registrant information

Name
reza rostami

Name of organization / entity
Rajaei heart center

Country
Iran (Islamic Republic of)

Phone
+98 21 6653 0401

Email address
rostami_reza755@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-20, 1398/05/29

Expected recruitment end date
2019-10-21, 1398/07/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The study of the effect of the use of Epinephrine, Norepinephrine and Phenylephrine drugs during cardiopulmonary bypass on brain oxygenation in patients undergoing open heart surgery

Public title
Comparison of the use of Epinephrine, Norepinephrine and Phenylephrine drugs during cardiopulmonary bypass on brain oxygenation

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patient satisfaction to participate in the study Patients undergoing elective open-heart surgery (Coronary artery bypass graft surgery and heart valve surgery) Patients older than 18 years No history of transient cerebral ischemic disease or stroke No history of narrowing of the carotid arteries by more than 70% or no clear stenosis No history of previous cardiac surgery Not having of uncontrolled diabetes (with the opinion of an internal specialist) or the absence of uncontrolled blood pressure (with the opinion of the cardiologist)

Exclusion criteria:
Heart arrest before starting cardiac bypass No need to prescribe inotropic drugs during surgery

Age
From **18 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method Will be performed as a six-point random block, and patients will be assigned to three groups according to the randomization list.

Blinding (investigator's opinion)
Double blinded

Blinding description
in this study,direction blind of the method six blocks are used. And practical none of the patients are aware of the grouping of drugs. In the beginning of the surgery, one of the three inotropic drugs was studied, without label and only on the basis of the randomization method at the disposal of the perfusionist who is responsible for the bypass.and he did not know the type of drug during the bypass pump. If the median arterial pressure drops to less than 50 mmHg, it will use a medication of one milliliter. As well as a person who records patient information does not have any sort of information grouping.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethict commitee of Shahid Rajaei Cardiovascular Medical and Research heart center

Street address
Shahid Rajaee Cardiovascular Center,valiasr street,Ayatollah Hashemi Highway,Tehran,iran

City
Tehran

Province
Tehran

Postal code
19956114331

Approval date
2019-04-27, 1398/02/07

Ethics committee reference number
IR.RHC.REC.1398.006

Health conditions studied

1

Description of health condition studied
hypotension

ICD-10 code
I95.8

ICD-10 code description
Other hypotension

Primary outcomes

1

Description
Brain Oxygenation

Timepoint
120, 150 and 180 seconds after injections of inotropic drugs during cardiopulmonary bypass.

Method of measurement
Monitoring of cerebral oxygen saturation

2

Description
Blood lactate level

Timepoint
Before the starting of cardiopulmonary bypass and during anesthesia,during cardiopulmonary bypasses at

certain intervals and after the end of the cardiopulmonary artery bypass.

Method of measurement

Arterial blood sample and arterial gas analyzer

3

Description

PH Level

Timepoint

Before starting of cardiopulmonary bypass and during anesthesia,During cardiopulmonary bypasses at certain intervals and after the end of the cardiopulmonary artery bypass.

Method of measurement

Arterial blood sample and arterial gas analyzer

4

Description

Duration of mechanical ventilation after surgery in patients

Timepoint

After surgery and in the intensive care unit

Method of measurement

The length of time the patient is in the intensive care unit is connected to the ventilator

5

Description

The duration of return of normal heart rhythm and the need for defibrillator and the need to use pacemakers

Timepoint

After surgery and in the intensive care unit

Method of measurement

Within 48 hours after the end of the pulmonary bypass

Secondary outcomes

1

Description

The rate of Use of Epinephrine, Norepinephrine and Phenylephrine for Maintaining Mean Arterial Pressure in the Range of 60 to 80 mmHg

Timepoint

At a time when the patient's blood pressure falls below 60 mm Hg during cardiopulmonary bypass

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: At the entrance to the operating room, patients will receive oxygen from the nasal cannula at 2 liters per minute. The ECG and average arterial blood pressure monitors and the cerebral-oxymeter system sensors will be connected to the patients before the start of anesthesia to determine the saturation of the brain oxygenation. Based on the random categorization of patients in the three groups during CPB to maintain and maintain the blood pressure of the patients Above 60 mmHg after increasing flow, if needed, a norepinephrine dose of 5 to 10 micrograms will be used. Arterial blood pressure, arterial oxygen saturation, and ScO2 will be recorded for each patient before the starting of anesthesia and the bypass. During the CPB period, the oxygen saturation saturation of 120, 150 and 180 seconds after injection of Inotrope drugs will be measured. The mean of arterial blood pressure, PaO2, body temperature of the patient, ScO2, will be displayed and recorded during the CPB period through the monitor. The mean arterial blood pressure and the measurement of the mean arterial pressure It will be done. ScO2 is also measured and displayed by brain oximetric monitors (INVOS, INVOS Somanetics, Troy, MI, USA).

Category

Treatment - Drugs

2

Description

Intervention group: At the entrance to the operating room, patients will receive oxygen from the nasal cannula at 2 liters per minute. The ECG and average arterial blood pressure monitors and the cerebral-oxymeter system sensors will be connected to the patients before the start of anesthesia to determine the saturation of the brain oxygenation. Based on the random categorization of patients in the three groups during CPB to maintain and maintain the blood pressure of the patients Above 60 mmHg after increasing flow, if needed, a Epinephrine dose of 5 to 10 micrograms will be used. Arterial blood pressure, arterial oxygen saturation, and ScO2 will be recorded for each patient before the starting of anesthesia and the bypass. During the CPB period, the oxygen saturation saturation of 120, 150 and 180 seconds after injection of Inotrope drugs will be measured. The mean of arterial blood pressure, PaO2, body temperature of the patient, ScO2, will be displayed and recorded during the CPB period through the monitor. The mean arterial blood pressure and the measurement of the mean arterial pressure It will be done. ScO2 is also measured and displayed by brain oximetric monitors (INVOS, INVOS Somanetics, Troy, MI, USA).

Category

Treatment - Drugs

3

Description

Intervention group: At the entrance to the operating room, patients will receive oxygen from the nasal cannula at 2 liters per minute. The ECG and average arterial blood pressure monitors and the cerebral-oxymeter system sensors will be connected to the patients before the start of anesthesia to determine the saturation of the brain oxygenation. Based on the random categorization of patients in the three groups during CPB to maintain and maintain the blood pressure of the patients Above 60 mmHg after increasing flow, if

needed, a Phenylephrine dose of 5 to 10 micrograms will be used. Arterial blood pressure, arterial oxygen saturation, and ScO2 will be recorded for each patient before the starting of anesthesia and the bypass. During the CPB period, the oxygen saturation saturation of 120, 150 and 180 seconds after injection of Inotrope drugs will be measured. The mean of arterial blood pressure, PaO2, body temperature of the patient, ScO2, will be displayed and recorded during the CPB period through the monitor. The mean arterial blood pressure and the measurement of the mean arterial pressure It will be done. ScO2 is also measured and displayed by brain oximetric monitors (INVOS, INVOS Somanetics, Troy, MI, USA).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Operation room of Shahid Rajaee Cardiovascular Center Tehran

Full name of responsible person
Reza Rostami

Street address
Shahid Rajaee Cardiovascular Center,Valiasr street

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Email
rostami_reza755@yahoo.com

Web page address
http://www.rhc.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Rajaee Cardiovascular Center Tehran

Full name of responsible person
Dr Mohsen Ziyaeifard

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Shahid Rajaee Cardiovascular Center ,Valiasr street

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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
Shahid Rajaee Cardiovascular Center Tehran

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
Shahid Rajaee Cardiovascular heart center

Full name of responsible person
Reza Rostami

Position
perfusionist

Latest degree
Master

Other areas of specialty/work
perfusion

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Shahid Rajaee Cardiovascular Center,Valiasr street,Ayatollah Hashemi Highway,Tehran,iran

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Web page address
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Reza Rostami

Position
Perfusionist
Latest degree
Master
Other areas of specialty/work
Perfusion
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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Privacy Patients
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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