

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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	Placebo Not used
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	Assignment Parallel
	Other design features
Public title Comparison of the use of Epinephrine, Norepinephrine and Phenylephrine drugs during cardiopulmonary bypass on brain oxygenation	Secondary Ids empty
Purpose Prevention	Ethics committees
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	1 Ethics committee Name of ethics committee Ethict committee of Shahid Rajaei Cardiovascular Medical and Research heart center Street address Shahid Rajaei Cardiovascular Center, valiasr street, Ayatollah Hashemi Highway, Tehran, iran City Tehran Province Tehran Postal code 19956114331
Age From 18 years old	Approval date 2019-04-27, 1398/02/07
Gender Both	Ethics committee reference number IR.RHC.REC.1398.006
Phase 1-2	Health conditions studied
Groups that have been masked • Participant • Data analyser	1 Description of health condition studied hypotension ICD-10 code I95.8 ICD-10 code description Other hypotension
Sample size Target sample size: 90	Primary outcomes
Randomization (investigator's opinion) Randomized	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
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.	2 Description Blood lactate level Timepoint Before the starting of cardiopulmonary bypass and during anesthesia,during cardiopulmonary bypasses at
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.	

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 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

City

Tehran

Province

Tehran

Postal code

1995614331

Phone

+98 21 23921

Fax

+98 21 2204 2026

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

Street address

Shahid Rajaee Cardiovascular Center ,Valiasr street

City

Tehran

Province

Tehran

Postal code

1995614331

Phone

+98 21 23921

Fax

+98 21 2204 2026

Email

mziyaeifard@yahoo.com

Web page address

http://rhc.ac.ir

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1444635458

Phone

+98 21 6653 9401

Email

rostami_reza755@yahoo.com

Web page address

http://hc.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

shahid rajai cardiovascular center

Full name of responsible person

Reza Rostami

Position
Perfusionist
Latest degree
Master
Other areas of specialty/work
Perfusion
Street address
Shahid Rajaei Cardiovascular Center, Valiasr
street, Ayatollah Hashemi Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
19956114331
Phone
+98 21 2392 2454
Fax
Email
rostami_reza755@yahoo.com
Web page address
<http://.rhc.ac.ir>

Person responsible for updating data

Contact
Name of organization / entity
Shahid Rajai Heart Center
Full name of responsible person
Reza Rostami
Position
Perfusionist
Latest degree
Master
Other areas of specialty/work
Perfusion
Street address
Shahid Rajaei Cardiovascular Center, Valiasr

street, Ayatollah Hashemi Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
19956114331
Phone
+98 23922454
Email
Rostami_reza755@yahoo.com
Web page address
<http://.rhc.ac.ir>

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