

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Evaluation the effect of pulsatile perfusion during cardiopulmonary bypass on cerebral tissue oxygenation and arterial blood lactate levels in patients undergoing valvular heart Surgery

Protocol summary

Summary

The main objective of this study is Evaluation the effect of pulsatile perfusion during cardiopulmonary bypass on cerebral tissue oxygenation and arterial blood lactate levels in patients undergoing valvular heart surgery, design the study is a randomized trial with a control group, 70 patients undergoing valvular heart surgery who have inclusion criteria randomly divided into two intervention and control groups. In the intervention group patients undergoing valvular heart surgery during aortic cross clamping time received pulsatile perfusion and in control group received routine perfusion (non pulsatile). The primary outcome variables are arterial lactate levels and cerebral oxygenation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101130266N1**

Registration date: **2017-08-26, 1396/06/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-26, 1396/06/04

Registrant information

Name

Samira Moosaei Far

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4686 1884

Email address

mosaeifar.s@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor Of Research, Iran University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of pulsatile perfusion during cardiopulmonary bypass on cerebral tissue oxygenation and arterial blood lactate levels in patients undergoing valvular heart Surgery

Public title

Evaluation the effect of pulsatile perfusion during cardiopulmonary bypass on cerebral tissue oxygenation and arterial blood lactate levels in patients undergoing valvular heart Surgery

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: patients with valvular heart disease that needs surgical replacement or repair of heart valves, body surface area less than 2, Age 18 to 65, Estimated cardiopulmonary bypass time greater than 60 minute, Left ventricle ejection fraction (LVEF) 40% and greater than 40% Exclusion criteria: patients with carotid

stenosis, atherosclerosis of ascending aorta and aortic arch, history of cerebrovascular accident, diabetic patient, hepatic disorders, alcoholism, patients needs emergency or complicated and redo surgeries, congenital heart disease, pregnancy, patients disagreement(without consent), preoperation arterial lactate levels greater than 2 milligram per deciliter, arteial blood gases not in normal rang during cardiopulmonary bypass, patients who needs intraaortic baloon pump(IABP), extracorporeal membrane oxygenation(ECMO) or patients with open sternum, cardiac arrest

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This study is randomized controlled clinical trial with blocked randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat highway, Tehran

City

Tehran

Postal code

Approval date

2016-11-21, 1395/09/01

Ethics committee reference number

IR.IUMS.REC 1395.9311584004

Health conditions studied

1

Description of health condition studied

Valvular heart disease

ICD-10 code

I134,I135,

ICD-10 code description

Nonrheumatic mitral valve disorders, Nonrheumatic aortic valve disorders, Nonrheumatic tricuspid valve disorders, Pulmonary valve disorders

Primary outcomes

1

Description

Arterial blood lactate level

Timepoint

after anasthasia and mechanical ventilation, after aortic cross clamping, after aortic cross clamp removal, termination of cardiopulmonary bypass, 2 and 4 hours post operation room

Method of measurement

arterial blood sample (our lab reference unit is milligram per decilitre)

2

Description

cerebral oxygenetion

Timepoint

During the whole time of surgery and cardiopulmonary bypass

Method of measurement

To evaluate cerebral oxygenetion we use INVOS cerebral /somatic oxymeter, the values are measured continuously as a percentage of oxygen saturation

Secondary outcomes

1

Description

Liver enzymes(AST& ALT)

Timepoint

Pre & Post operation

Method of measurement

blood sample(our lab reference unit is Unit per liter)

2

Description

Renal function tests(BUN & Cr)

Timepoint

Pre & Post operation

Method of measurement

blood sample(our lab reference unit is milligram per deciliter)

3

Description

Lactate dehydrogenase(LDH)

Timepoint

Pre & Post operation

Method of measurement

blood sample(our lab reference unit is Unit per liter)

4**Description**

Platelet count

Timepoint

Pre & Post operation

Method of measurement

blood sample(our lab reference unit is platelete count per microliters)

5**Description**

Urine out put

Timepoint

Pre CPB, Pre aortic cross clamp, after removal of aortic cross clamp, termination of CPB

Method of measurement

Through direct vision urine volume(in millilite)r is measured by collecting in urine bag

Intervention groups**1****Description**

During open heart surgery when patient is on cardiopulmonary bypass after aortic cross clamping and cardioplegic arrest patients undergoing pulsatile perfusion. pulsatile features on heart lung machine set as following: frequency: 70 beat per minute, pulse width: 50%, base flow: 30%(70%pulsatile and 30% nonpulsatile)

Category

Other

2**Description**

In control group during cardiopulmonary bypass after aortic cross clamping patients undergoing routine(non pulsatile) perfusion.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Rajayi Cardiac Hospital

Full name of responsible person**Street address**

Shahid Rajayi Cardiac Hospital, Niayesh Highway, Valiasr Street, Tehran

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor Of Research, Iran University of Medical Sciences

Full name of responsible person

Seyyed Ali Javad Moosavi

Street address

Iran University of Medical Sciences, Shahid Hemmat highway, Tehran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor Of Research, Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Samira Moosaei Far

Position

Post Graduate Student in Cardiovascular Perfusion Technology

Other areas of specialty/work**Street address**

School of Nursing & Midwifery, Shahid Rashid Yasemi Street, Valiasr Street, Tehran

City

Tehran

Postal code**Phone**

+98 919 165 0136

Fax**Email**

samira.moosaei@gmail.commosaeifar.s@tak.iums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nursing & Midwifery of Iran University of Medical Sciences

Full name of responsible person

Tahereh Najafi Ghezalje

Position

Ph.D in Nursing

Other areas of specialty/work**Street address**

School of Nursing & Midwifery, Shahid Rashid Yasemi Street, Valiasr Street, Tehran

City

Tehran

Postal code**Phone**

+98 21 4365 1000

Fax**Email**

najafi.t@iums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Samira Moosaei Far

Position

Post Graduate Student in Cardiovascular Perfusion Technology

Other areas of specialty/work**Street address**

School of Nursing & Midwifery, Shahid Rashid Yasemi Street, Valiasr Street, Tehran

City

Tehran

Postal code**Phone****Fax****Email**

samira.moosaei@gmail.com
mosaeifar.s@tak.iums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty