Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of regulating the flow rate of cardiopulmonary bypass pump based on lean body mass index on mixed venous blood oxygen and arterial blood lactat level among patients with abnormal range of body mass index

Protocol summary

Summary

Main objective: effect of calculated blood flow rate based on Lean Body Mass Index during Cardiopulmonary Bypass on mixed venous oxygen saturation and arterial blood lactate level among patients with abnormal Body Mass Index. This study was designed as a randomized clinical trial with a control group which will be done in patients with body mass index more than 25. Setting: in this study, 152 patient undergoing Cardiac Surgery by Cardiopulmonary Bypass are classified randomly in two groups of intervention and control. Patients specifically are chosen between body mass index range of 25-35 which have been defined as overweight (body mass index 25-29) and obese (body mass index 30-35). Inclusion criteria are, 18-70-year-old patients who do not have history for respiratory, renal and hepatic disease, more than 70% one-side or 50% two-side carotid stenosis and cardiac surgery by Cardiopulmonary Bypass. pump Flow Rate for each patient is calculated based on Lean Body Mass In intervention group and Body Surface Area in control group. Research variables are blood lactate level and mixed venous oxygen saturation which are supposed to be measured in specified periods

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012932276N1**
Registration date: **2017-06-27, 1396/04/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-27, 1396/04/06

Registrant information

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Recruitment status

Recruitment complete

Funding source
Vice Chancellor for research, Iran University of Medical Science

Expected recruitment start date
2017-05-19, 1396/02/29

Expected recruitment end date
2017-07-21, 1396/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of regulating the flow rate of cardiopulmonary bypass pump based on lean body mass index on mixed venous blood oxygen and arterial blood lactat level among patients with abnormal range of body mass index

Public title

The effect of regulating the flow rate of cardiopulmonary

bypass pump based on lean body mass index on mixed venous blood oxygen and arterial blood lactat level among patients with abnormal range of body mass index

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1، Older than 18 years old 2، body mass index of between 25-35 3،open heart surgery with the use of cardiopulmonary bypass 4،not having disorder in kidney, lung, liver and cerebral and treatment-resistant hypertension 5, left ventricular ejection fraction more than 30% 6، patients with bilateral carotid artery stenosis greater than 50% or unilateral carotid stenosis greater than 70% 7,patients elective open heart surgery exclusion criteria from the study: 1 , any event that affect the normal process of open heart surgery include cardiopulmonary bypass requirement though surgery, persistent decline of blood pressure through cardiopulmonary bypass that not respond to Inotropic drug 2, death 3, aortic clamping time over 100 minutes 4, temperature reduction below 28 degree during operation for any reason the surgeon decide to catch a lower temperature than 28 degree

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **152**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Allocation of samples in the form of blocks Random can be done using a computer

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran Univercity of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat highway, Tehran, Iran

City

Tehran

Postal code

1449614535

Approval date

2017-03-04, 1395/12/14

Ethics committee reference number

IR.IUMS.REC 1395.9311584005

Health conditions studied

1

Description of health condition studied

Heart disease

ICD-10 code

I25.0

ICD-10 code description

Atherosclerotic cardiovascular disease, so described

Primary outcomes

1

Description

on mixed venous oxygen saturation

Timepoint

after anesthesia,during cardiiopulmonary bypass,after cardiopulmonary bypass

Method of measurement

content of each gas in arterial blood Under the pressure of eac gas

2

Description

arterial blood lactate

Timepoint

after anesthesia,during cardiiopulmonary bypass,after cardiopulmonary bypass

Method of measurement

arterial blood sample

Secondary outcomes

1

Description

o2 consumption

Timepoint

during cardiopulmonary bypass

Method of measurement

content of each gas in venous blood Under the pressure of eac gas and pump flow rate

Intervention groups

1

Description

In this study, in the intervention group, patients with BMI

over 25, obtained number from lean body mass will be multiplied by 2.4 and according to it pump flow will be arranged in cardiopulmonary bypass machine. After anesthesia, first blood sample will be taken using 2 ml heparinized syringe from radial artery and the venous blood sample will be taken from the central venous. Second blood sample will be obtained after cross-clamped of the aorta and cardioplegia induction. During rewarming and after declamping in temperature between 35-37 degree, third sample will be taken from oxygenator arterial line sample and venous reservoir entrance, respectively. In case of long surgery procedures, sampling will be repeated every half an hour. Finally, based on gained samples, measuring arterial lactate level and mixed venous oxygen saturation will be done.

Category

Prevention

2

Description

In this study, in the control group, patients with BMI over 25, obtained number from bodr sueface area will be multiplied by 2.4 and according to it pump flow will be arranged in cardiopulmonary bypass machine. After anesthesia, first blood sample will be taken using 2 ml heparinized syringe from radial artery and the venous blood sample will be taken from the central venous. Second blood sample will be obtained after cross-clamped of the aorta and cardioplegia induction. During rewarming and after declamping in temperature between 35-37 degree, third sample will be taken from oxygenator arterial line sample and venous reservoir entrance, respectively. In case of long surgery procedures, sampling will be repeated every half an hour. Finally, based on gained samples, measuring arterial lactate level and mixed venous oxygen saturation will be done

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

rajaei cardiovascular, medical& reaserch center

Full name of responsible person

Parvin Vahid

Street address

Rajaei Cardiovascular, Medical & reaserch center, ValiAsr and Niayesh expy intersection

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

iran univercity of medical science

Full name of responsible person

Technology and Research Deputy of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat highway

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

iran univercity of medical science

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 Science

Full name of responsible person

Parvin Vahid

Position

masters student of cardiovascular perfusion technology

Other areas of specialty/work

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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