

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Clinical Trial of Assessment of the effect of high flow of cardiopulmonary pump on the laboratory findings and cerebral perfusion in patients undergo open heart surgery

Protocol summary

Study aim

Determining level of serum urea, creatinine, liver enzymes, consciousness level, arterial blood gases and cerebral oxygenation before ,during and after surgery in patients undergoing open heart surgery, separating two groups of normal flow and high flow

Design

A randomized, controlled, phase 3 clinical trial on 60 patients.

Settings and conduct

The preparation conditions before and during the operation will be completely the same for the patients of both groups. Such as the amount and composition of the solutions used for priming, the same oxygenators, the same method of induction and maintenance of anesthesia, and also during the establishment of the cardiopulmonary pump, mild hypothermia will be used in both groups of patients. During the entire study, in order to avoid bias, one surgeon and one perfusionist will be present in all operations.

Participants/Inclusion and exclusion criteria

Entry criteria include: Candidate for open heart surgery; Non-entry criteria include: Patients with congestive heart failure or cardiac EF below 30%; Patients who need an intra-aortic balloon pump; Duration of aortic clamp more than 2 hours and surgery more than 3 hours; Patients with a history of stroke, any disorder of level of consciousness before the operation; Patients with chronic renal failure or undergoing hemodialysis; The occurrence of any unpredictable conditions and malfunction of the pump during surgery;

Intervention groups

Normal flow :a flow rate of 2.4 liters per square meter per minute is used, which is the usual flow rate used during open heart surgery. High flow: a flow rate of 2.6 liters per square meter per minute is used.

Main outcome variables

The aim of study is investigating the effect of high flow cardiopulmonary pump on the level of urea creatinine, Liver enzymes, consciousness, brain tissue oxygenation , serum electrolyte, lactate in patients undergoing surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231022059804N1**

Registration date: **2023-10-27, 1402/08/05**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-27, 1402/08/05**

Update count: **0**

Registration date

2023-10-27, 1402/08/05

Registrant information

Name

Muhamad Dastkhan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3276 4522

Email address

dastkhan321@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-24, 1402/08/02

Expected recruitment end date

2023-12-23, 1402/10/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial of Assessment of the effect of high flow of cardiopulmonary pump on the laboratory findings and cerebral perfusion in patients undergo open heart surgery

Public title

Assessment of the effect of high flow of cardiopulmonary pump on the laboratory findings and cerebral perfusion in patients undergo open heart surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Admission in the Open Heart ICU of Kowsar hospital
Candidate for undergoing open heart surgery
Obtaining a written consent for entering to the study

Exclusion criteria:

Patients with EF under 30%
Patients who need Intra-aortic balloon pump
Any unpredictable event during the surgery or Malfunction of Cardiopulmonary pump
Aorta clamping lasts more than 2 hours
The whole surgery lasts more than 3 hours
Patients with history of CVA
Patients with Congestive Heart Failure
Patients with the history of chronic kidney disease and undergoing dialysis
Patients with the history of chronic renal failure or undergoing hemodialysis
Due to the fact that during the surgery the amount of PFR changes depending on the conditions of the operation, in case of fluctuation, the PFR may reach a level that reaches another group

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked*No information***Sample size**

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

From the start date of the project eligible patients entered the study, these patients are randomly divided into two groups. Randomization is done using a table of random numbers. One group receives normal and standard flow and the other group receives high flow.

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 Semnan University of Medical Sciences

Street address

Kpwsar educational research and treatment center,
Golestan Town, Semnan,

City

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Province

Semnan

Postal code

3519899951

Approval date

2022-06-27, 1401/04/06

Ethics committee reference number

IR.SEMUMS.REC.1401.097

Health conditions studied**1****Description of health condition studied**

Open Heart Surgery using cardiopulmonary pump

ICD-10 code

I97.820

ICD-10 code description

Postprocedural cerebrovascular infarction during cardiac surgery

2**Description of health condition studied**

Coronary artery bypass grafting

ICD-10 code

I25.719

ICD-10 code description

Atherosclerosis of autologous vein coronary artery
bypass graft(s) with unspecified angina pectoris

Primary outcomes**1****Description**

Blood Urea Nitrogen

Timepoint

1 day before and 1 day after surgery

Method of measurement

Blood sample test

2

Description

Serum Creatinine

Timepoint

1 day before and 1 day after surgery

Method of measurement

Blood sample test

3

Description

Alkaline phosphatase serum level

Timepoint

1 day before and 1 day after surgery

Method of measurement

Blood sample test

4

Description

Aspartate aminotransferase serum level

Timepoint

1 day before and 1 day after surgery

Method of measurement

Blood sample test

5

Description

Alanine transaminase serum level

Timepoint

1 day before and 1 day after surgery

Method of measurement

Blood sample test

6

Description

The consciousness level of patient

Timepoint

Before surgery in OR and after surgery in recovery room

Method of measurement

The consciousness level of patient, which is evaluated by anesthesiologist in 4 levels. 1. Patient is alert: the patient is awake with his eyes open and answers the questions. It doesn't matter if the answers are imprecise or incorrect. 2. Responds to the Verbal stimulus: the patient only uses unintelligible sounds in answering the questions. 3. Responds to the pain stimulus: the patient only responds to pain. This response is either associated with the removal of the pain agent or only with stretching and expansion in the limbs. 4. No response: The patient is without any response to sound and pain.

7

Description

Cerebral Oxygenation

Timepoint

During surgery

Method of measurement

Cerebral Oximeter

8

Description

Serum electrolytes level (Sodium, potassium and calcium)

Timepoint

Before , during(every 30 minutes) and after surgery

Method of measurement

Blood sample test

9

Description

Serum Lactate Level

Timepoint

Before , during(every 30 minutes) and after surgery

Method of measurement

Blood sample test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: High flow group: In this group of patients, a flow rate of 2.6 liters per square meter per minute is used.

Category

Treatment - Surgery

2

Description

Control group: Normal flow group: In this group, a flow rate of 2.4 liters per square meter per minute is used to establish the flow of the cardiopulmonary pump, which is the usual flow rate used during open heart surgery.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Kausar Medical Research Training Center

Full name of responsible person

Muhamad Frouzeshfard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Muhamad Frouzeshfard

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Muhamad Frouzeshfard

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Muhamad Dastkhan

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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