Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Vacuum Assisted Venous Drainage on Kidney Function and Blood Transfusion in Patients Undergoing Cardiac reoperation

Protocol summary

Study aim
Determining The Effect of Vacuum Assisted Venous Drainage (VAVD) on Kidney Function and Blood Transfusion in Patients Undergoing Cardiac reoperation

Design
A randomized, controlled, double-blinded, paralleled clinical trial on 90 patients

Settings and conduct
90 patients who are candidates for cardiac reoperation referred to Tehran Shaheed Rajaie Cardiovascular Medical and Research Center will be divided into two groups if they meet the inclusion criteria using random blocks of size 6. All anesthesia and cardiopulmonary bypass (CPB) conditions will be similar in patients and the only difference will be the use of VAVD during CPB in the intervention group. Patients and intensive care unit (ICU) nurses will not be aware of the use or non-use of VAVD during CPB

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients who are candidates for cardiac reoperation, Informed consent to participate in the study, Age more than 18 years, Ejection Fraction (EF) greater than 35%; Exclusion criteria: Presence of large vessel surgeries requiring Deep Hypothermic Circulatory Arrest (DHCA), third time reoperation and more, Presence of kidney failure before surgery (patient with previous diagnosis of kidney failure or creatinine higher than 1.5 mg/dL), Presence of History of bleeding disorders before surgery, Presence of Anemia before surgery (hemoglobin less than 10 gr/dL), Presence of history of cerebrovascular diseases

Intervention groups
In the patients undergoing cardiac reoperation in the intervention group, venous drainage will be performed using VAVD, but in the control group, venous drainage will be based on gravity and the height difference between the patient and the oxygenator

Main outcome variables
The average level of serum creatinine up to 48 hours after surgery and the occurrence of acute kidney injury based on the KDIGO (Kidney Disease Improving Global Outcomes) criteria

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230915059434N1**
Registration date: **2023-10-14, 1402/07/22**
Registration timing: **prospective**

Last update: **2023-10-14, 1402/07/22**
Update count: **0**

Registration date
2023-10-14, 1402/07/22

Registrant information

Name
Zahra Majidi parizi

Name of organization / entity
Shaheed Rajaie Cardiovascular Medical and Research Center

Country
Iran (Islamic Republic of)

Phone
+98 21 23921

Email address
zahra.majidiparizi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-01, 1402/08/10

Expected recruitment end date
2024-05-30, 1403/03/10

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Vacuum Assisted Venous Drainage on Kidney Function and Blood Transfusion in Patients Undergoing Cardiac reoperation

Public title
The Effect of Vacuum Assisted Venous Drainage (VAVD) on Kidney Function and Blood Transfusion

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who are candidates for cardiac reoperation Informed consent to participate in the study Age more than 18 years (Left Ventricular Ejection Fraction) LVEF greater than 35%

Exclusion criteria:
Presence of large vessel surgeries requiring Deep Hypothermic Circulatory Arrest (DHCA), third time reoperation and more Presence of kidney failure before surgery (patient with previous diagnosis of kidney failure or creatinine higher than 1.5 mg/dL) Presence of History of bleeding disorders before surgery Presence of Anemia before surgery (hemoglobin less than 10 gr/dL) Presence of history of cerebrovascular diseases

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided into two groups using a random block method with a size of 6: 45 patients in the VAVD group (receiving VAVD during cardiopulmonary bypass) and 45 patients in the GD group (venous drainage with gravity only)

Blinding (investigator's opinion)
Double blinded

Blinding description
After obtaining informed consent, due to being under anesthesia and surgery, the patients will not know whether they will be assigned to the control or intervention group and ICU nurses will not know about the use or non use of VAVD during cardiopulmonary bypass.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Rajaie Cardiovascular Medical and Research Center

Street address
Shaheed Rajaie Cardiovascular Medical and Research Center, Valiasr Ave, Niayesh Intersection

City
Tehran

Province
Tehran

Postal code
1995614331

Approval date
2023-08-05, 1402/05/14

Ethics committee reference number
IR.RHC.REC.1402.052

Health conditions studied

1

Description of health condition studied
Cardiac reoperation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Serum creatinine level

Timepoint
Preoperatively, upon admission to the intensive care unit, 24 and 48 hours later

Method of measurement
laboratory test

Secondary outcomes

1

Description
Blood Urea Nitrogen

Timepoint
Preoperatively, upon admission to the intensive care unit, 24 and 48 hours later

Method of measurement

laboratory test

2

Description
The amount of urinary output
Timepoint
During cardiopulmonary bypass, 6, 12, 24 and 48 hours after surgery
Method of measurement
Patient file information

3

Description
Central Venous Pressure
Timepoint
Before starting bypass, During and after the completion of cardiopulmonary bypass, upon entering the intensive care unit, 6, 12, 24 and 48 hours after surgery
Method of measurement
Patient monitoring information

4

Description
Mean Arterial Pressure
Timepoint
Before starting bypass, During and after the completion of cardiopulmonary bypass, upon entering the intensive care unit, 6, 12, 24 and 48 hours after surgery
Method of measurement
Patient monitoring information

5

Description
Prime volume used in cardiopulmonary bypass circuit
Timepoint
The volume of fluid used in the circuit at the start of cardiopulmonary bypass
Method of measurement
Patient file information

6

Description
Hemoglobin
Timepoint
Preoperatively, before starting bypass, during and after completion of cardiopulmonary bypass, upon admission to the intensive care unit, 6, 12, 24, and 48 hours after surgery
Method of measurement
laboratory test

7

Description
The amount of blood transfusion
Timepoint
Up to 48 hours after surgery
Method of measurement
Patient file information

Intervention groups

1

Description
Intervention group: In the intervention group, by using the Polystan VAVD Controller and reducing the height difference between the patient and the venous reservoir, the length of the cardiopulmonary bypass circuit lines will be reduced to reduce the volume of the primary bypass circuit by 250 cc. Throughout the use of Vacuum Assisted Venous Drainage(VAVD), the negative pressure of the venous reservoir will be monitored and controlled in the range of -30 to -45 mm Hg.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shaheed Rajaie Cardiovascular Medical and Research Center
Full name of responsible person
Zahra Majidi Parizi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shaheed Rajaie Cardiovascular Medical and Research Center
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
Shaheed Rajaie Cardiovascular Medical and Research Center
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
Shaheed Rajaie Cardiovascular Medical and Research Center
Full name of responsible person
Zahra Majidi Parizi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Extracorporcal Circulation Technology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All information related to the study procedure and its consequences can be provided

When the data will become available and for how long

After publishing the articles from the study, the data will be available.

To whom data/document is available

All researchers in the field of medical sciences

Under which criteria data/document could be used

With scientific purposes and with the author's knowledge

From where data/document is obtainable

To access the data, you can contact the researcher Zahra Majidi via e-mail zahra.majidiparizi@gmail.com and the address of Tehran, Shaheed Rajaie Heart Hospital.

What processes are involved for a request to access data/document

After communicating with the researcher via email or address and fully introducing the applicant and stating the purpose of using the data, it will be possible to access the data in less than a month.

Comments