Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the Effect of Pulsatile and Non-pulsatile Perfusion Flow on Renal Function during Coronary Artery Bypass Grafting Surgery in Patients with Left Ventricular Dysfunction

Protocol summary

Study aim

Determination and Comparison of Effect of Pulsatile and Non-pulsatile Perfusion Flow on Renal Function in Coronary Artery Bypass Grafting Surgery in Patients with Left Ventricular Dysfunction

Design

This is a randomized, double-blind clinical study.Patients were randomly divided into two groups by using coin pellet. The sample size is 64 patients, 40 of them received non-pulsatile flow and 24 of them received pulsatile flow.

Settings and conduct

Type: randomized clinical trial /double-blind by co-researcher/done for 64 patients: 40 received non-pulsatile and 24 pulsatile flow/location: heart surgery room of Namazi hospital

Participants/Inclusion and exclusion criteria

Study Entry Criteria: Patients referred to the heart surgery room for elective CABG in Shiraz University of Medical Sciences affiliated hospitals Participation Satisfaction in the research project Left ventricular dysfunction(EF≤40%). Coronary artery bypass surgery age range 40-75 years Exit criteria: Patient's unwillingness to continue participation Simultaneous Surgical operation of the valve and coronary artery Risk of anesthesia greater than three Systemic infection or Sepsis Renal dysfunction (Cr> 1.5). Liver Dysfunction Redo the recent records of stroke Concurrent autoimmune disease History of taking any immunosuppressive medicine, chemotherapy or radiotherapy.

Intervention groups

the Control and the Case Group: Among patients candid CABG who suffer from Left Ventricular Dysfunction, the group who received the Pulsatile Flow was selected as the case group and the group that received the non-Pulsatile Flow was selected as the control group

Main outcome variables

Renal parameters include Cr, BUN, GFR and 24-hour UO. Non-renal parameters during and after surgery include blood intake, colloid, crystalloid, bleeding rate, urine rate, inotropic and furosemide intake rate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190218042749N1**
Registration date: **2019-07-15, 1398/04/24**
Registration timing: **retrospective**

Last update: **2019-07-15, 1398/04/24**
Update count: **0**

Registration date

2019-07-15, 1398/04/24

Registrant information

Name
Marzieh Zamani Jahromi
Name of organization / entity
Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 71 5426 7727
Email address
marziehzamani@jums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-08-21, 1397/05/30

Actual recruitment start date

2018-01-21, 1396/11/01

Actual recruitment end date

2018-08-18, 1397/05/27

Trial completion date

2018-08-21, 1397/05/30

Scientific title

Comparison of the Effect of Pulsatile and Non-pulsatile Perfusion Flow on Renal Function during Coronary Artery Bypass Grafting Surgery in Patients with Left Ventricular Dysfunction

Public title

The Effect of Pulsatile and Non-pulsatile Perfusion Flow on Renal Function during Coronary Artery Bypass Grafting Surgery in Patients with Left Ventricular Dysfunction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients referring to Operation room for Elective CABG in dependent hospitals to Shiraz University of Medical Sciences participation satisfaction in attending the project left Ventricular dysfunction Bypass Coronary Grafting Surgery enjoying EF pulsatile lower than 40 percent(based on Suggestions from American Cardiography Association) equivalent to severe left ventricular dysfunction Ages from 40 to 75

Exclusion criteria:

lack of patient's tendency to continue the study simultaneous surgery of Valve and Coronary Anesthesia risk more than 3 Sepsis Renal dysfunction (Cr>1.5) Redo Liver Dysfunction Records of brain stroke Concurrent autoimmune diseases Records of immunosuppressive drugs, Chemotherapy or radiotherapy emergency patients

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Actual sample size reached: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients participating in the study were divided into two intervention and control groups by throwing coins.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study: participants, the researcher, medical staff(physicians and nurses), those responsible for data collection, the individuals who analyzed the final results, and those who prepared the paper draft.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Central Building of Medical Sciences University, Across from Felestin St., Zand St.,

City

Shiraz

Province

Fars

Postal code

۱۴۳۳۶ - ۷۱۳۴۸

Approval date

2017-10-23, 1396/08/01

Ethics committee reference number

IR.SUMS.REC.1397.108

Health conditions studied

1

Description of health condition studied

Patients who have Coronary Artery Disease candidate of CABG with left ventricular dysfunction

ICD-10 code

I25.708

ICD-10 code description

Atherosclerosis of coronary artery bypass graft(s), unspecified, with other forms of angina pectoris

Primary outcomes

1

Description

Renal parameter UO24h

Timepoint

Before bypass surgery, During bypass surgery, three days after bypass surgery,

Method of measurement

Laboratory variables were sent to the laboratory and got

analyzed with the related devices. 24-hour urine volume after the surgery was measured by the ICU nurses.

2

Description
Renal parameter BUN
Timepoint
Before bypass surgery, During bypass surgery, three days after bypass surgery,
Method of measurement
Laboratory variables were sent to the laboratory and got analyzed with the related devices. 24-hour urine volume after the surgery was measured by the ICU nurses.

3

Description
Renal parameter GFR
Timepoint
Before bypass surgery, During bypass surgery, three days after bypass surgery,
Method of measurement
Laboratory variables were sent to the laboratory and got analyzed with the related devices. 24-hour urine volume after the surgery was measured by the ICU nurses.

4

Description
Renal parameter Cr
Timepoint
Before bypass surgery, During bypass surgery, three days after bypass surgery,
Method of measurement
Laboratory variables were sent to the laboratory and got analyzed with the related devices. 24-hour urine volume after the surgery was measured by the ICU nurses.

Secondary outcomes

1

Description
BMI
Timepoint
Before bypass surgery
Method of measurement
Based on Patient's File

2

Description
Bleeding rate
Timepoint
three days after bypass surgery in ICU
Method of measurement
Bleeding rate was determined based on the scaled chest bottle tube.

3

Description
Gender
Timepoint
Before bypass surgery
Method of measurement
Based on Patient's File

4

Description
Age
Timepoint
Before bypass surgery
Method of measurement
Based on Patient's File

5

Description
EF
Timepoint
Before bypass surgery
Method of measurement
Based on Patient's File

Intervention groups

1

Description
Control group: CABG candid patients who suffer from left ventricular dysfunction and received non-pulsatile flow during the surgery via Pump machine
Category
Treatment - Surgery

2

Description
Intervention group: CABG candid patients who suffers from left ventricular dysfunction and received pulsatile flow during the surgery via Pump machine
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi Hospital
Full name of responsible person
Marzieh Zamani
Street address
Namazi sq., Shiraz
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

Street address

Research Secretary, 7th Floor, Central Building of Shiraz University of Medical Sciences, Zand St., Shiraz

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Shiraz

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71345-1978

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+98 71 3235 7282

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vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Marzieh Zamani Jahromi

Position

MSc student of Perfusion

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

Street address

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http://jums.ac.ir/Index.aspx?page_=form&lang=1&sub=4&tempname=OmooreEdari&PageID=18044&isPopUp=False

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

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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

Patients identity information such as first name, last name, file No. and Hospitalization code are not recorded.

When the data will become available and for how long

from March-2019

To whom data/document is available

Professors, University students and all researches who study the same issue.

Under which criteria data/document could be used

In order to get information about different aspects of specialized and applied purposes, hypothesis, research methods, and results in order to be used with citations as a reference in future studies.

From where data/document is obtainable

Library of Shiraz University of Medical Sciences and Anaesthesia Department Library located at Shiraz University of Medical Sciences

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

The applicant can find access to data after presenting his/her personal ID card with this explanation that he/she is not allowed to take photos of the document or to take it out of the library.

Comments