

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($EF \leq 40\%$). 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
 ۷۱۳۳۶ - 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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Shiraz

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13311 - 71936

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marziehzamani@jums.ac.ir

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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71345-1978

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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

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Motahari St.,Pardis Site, After Nursing College,
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http://jums.ac.ir/Index.aspx?page_=form&lang=1&su
b=4&tempname=OmooreEdari&PageID=18044&isPo
pUp=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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b=4&tempname=OmooreEdari&PageID=18044&isPo
pUp=False

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Marzieh Zamani Jahromi

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Latest degree

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Web page address

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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