

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Review and compare of renal function in pulsatile and non-pulsatile perfusion in patient undergoing coronary artery surgery.

Protocol summary

Study aim

Review and compare of renal function in pulsatile and non-pulsatile perfusion in patient undergoing coronary artery surgery

Design

Double blind clinical trial by two groups of patients with pulsatile perfusion and non-pulsatile perfusion 25 patients in each group (50 patients generally) in parallel analyzing with spss software.

Settings and conduct

Patients undergoing coronary artery surgery were accidentally chosen to the study surgeon nurses patients and researcher were not aware about the kind of perfusion applied during surgery

Participants/Inclusion and exclusion criteria

Entrance criterions: Age above 18 years Coronary artery surgery Exit criterions: Suffering MI in the last two weeks Off pump surgery Urgent surgery Untreated diabetes Abnormal liver function Reduced level of consciousness before surgery

Intervention groups

Intervention group: Patients undergoing coronary surgery with pulsatile blood flow of pump After getting anesthesia and opening the chest, patients were connected to the heart-lung machine that was set on pulsatile mode. Control group: Patients undergoing coronary surgery with nonpulsatile blood flow of pump In this group like the intervention group after anesthesia and opening the chest patients were connected to heart-lung machine that was set nonpulsatile.

Main outcome variables

Renal function by analyzing urine output during surgery and 24 hours after surgery, amounts of GFR at the time of releasing from hospital, amounts of BUN 24 hours after surgery and at the time of releasing from hospital, amounts of serum creatinine 24 hours after surgery and at the time of releasing from hospital, amounts of blood sodium and potassium during surgery and after surgery analyzing these parameters in both groups and

comparing these between two groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048509N1**

Registration date: **2020-09-19, 1399/06/29**

Registration timing: **retrospective**

Last update: **2020-09-19, 1399/06/29**

Update count: **0**

Registration date

2020-09-19, 1399/06/29

Registrant information

Name

Sahra Salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3650 2537

Email address

sahasalehi90@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

2019-09-23, 1398/07/01

Actual recruitment end date

2020-01-21, 1398/11/01

Trial completion date

2020-01-21, 1398/11/01

Scientific title

Review and compare of renal function in pulsatile and non-pulsatile perfusion in patient undergoing coronary artery surgery.

Public title

Renal function in pulsatile and non-pulsatile perfusion in patient undergoing coronary artery surgery.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age above 18 years Coronary artery surgery

Exclusion criteria:

Suffering MI in the last two weeks Off pump surgery
Urgent surgery untreated diabetes Abnormal liver
function Reduced level of consciousness before surgery

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Surgeon and the nurse involved in the study were not aware of the kind of perfusion applied to the patient

Blinding (investigator's opinion)

Double blinded

Blinding description

Surgeon and the nurses involved in the study were not aware of the kind of perfusion applied to the patients

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd Shahid Sadoughi University
of medical sciences

Street address

Bostan Ave, South Valieasr Blv, Baharestan, Isfahan.

City

Yazd

Province

Yazd

Postal code

8143176944

Approval date

2019-07-06, 1398/04/15

Ethics committee reference number

IR.SSU.MEDICINE.REC.1398.121

Health conditions studied

1

Description of health condition studied

Coronary artery disease

ICD-10 code

I25

ICD-10 code description

Chronic ischemic heart disease

Primary outcomes

1

Description

Change in renal function

Timepoint

Before surgery, during surgery, 24 hours after surgery, at
the releasing time from hospital.

Method of measurement

Getting blood and urine sample

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group of patients undergoing coronary artery surgery with pulsatile blood flow of pump At the open heart surgery room, after anesthesia and opening the patients chest, patients were connected to the heart-lung mashine and in this study the heart-lung mashine was run in pulsatile blood flow mode in the intervention group, urine and blood samples were collected to measure the related variables to renal function such as: blood sodium and potassium before during and after surgery, Creatinine and BUN before surgery 24 hours after surgery and at releasing time from hospital, urine output before surgery 24 hours after surgery and at releasing time from hospital, and GFR before surgery and at releasing time from hospital.

Category

Treatment - Devices

2

Description

Control group: Group of patients undergoing coronary artery surgery with non-pulsatile blood flow of pump. In this group after connecting to the heart-lung machine the blood flow was administered non-pulsating and all of the variables related to renal function such as: blood sodium and potassium before during and after surgery, Creatinine and BUN before surgery 24 hours after surgery and at releasing time from hospital, urine output before surgery 24 hours after surgery and at releasing time from hospital, and GFR before surgery and at releasing time from hospital were collected and measured. In order to compare the variable between two groups spss software was used to see if the differences are statistically significant or not.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiac department of Bandarabbas Shahid Mohammadi general hospital

Full name of responsible person

Sahra Salehi

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Bostan Ave, South Valieasr Blv, Baharestan, Isfahan

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Email

Sahrasalehi90@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaee

Street address

Bostan Ave, Valieasr Blv, Baharestan, Isfahan

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Email

Sahrasalehi90@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd University of Medical Sciences

Proportion provided by this source

1

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

2

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaee

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Yes

Title of funding source

Yazd University of Medical Sciences

Proportion provided by this source

1

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

Yazd University of Medical Sciences

Full name of responsible person

Sahra Salehi

Position

Cardiopulmonary Perfusionist

Latest degree

Master

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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Fax**Email**

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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