Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Determination and comparison of the effect of 30 and 70 pulses in pulsatile cardiopulmonary bypass on clinical outcome of patients undergoing Coronary Artery Bypass Graft (CABG) surgery

Protocol summary

Study aim

Determination and comparison of the effect of 30 and 70 pulses in pulsatile cardiopulmonary bypass on clinical outcome of patients undergoing Coronary Artery Bypass Graft (CABG) surgery

Design

Randomised ; Controlled ; Unilateral blinded ; Six blocks ; 90 patients

Settings and conduct

In this study, patients who refer to the operating room of Shahid Rajaei Heart Hospital in Tehran and are on the list of coronary artery bypass graft surgery and have entry criteria are examined. Patients are randomly divided into three groups: group A 30 pulses per minute - group B 70 pulses per minute - group C receives non-pulsating perfusion. All patients under study will have the same anesthesia and pump conditions. After the pump starts and immediately after the aortic clamp, the pulsating current will start, and after removing the clamp, the aorta will end and the pump will continue with the continuous flow.

Participants/Inclusion and exclusion criteria

1. Patient satisfaction to enter the study 2- Patients in the age range of 40-65 years 3- Elective patients of CABG surgery under cardiopulmonary bypass 4. Patients with EF above 30% 5. No history of heart surgery 6- No other processor with CABG 7- Lack of liver failure as ALT> 40 units / l AST> 40 units / l 8. No preoperative pulmonary dysfunction test as FEV1 <65% 9- No creatine level higher than 2 mg/dl 10- Lack of hemoglobin level less than 10 mg/dl

Intervention groups

In the pump settings, the A group receives 30 pulse per minute - the B group receives 70 pulses per minute - the C group receives non-pulsating perfusion.After the pump starts and immediately after the aortic clamp, the pulsating current will start and after removing the clamp of aorta will end.

Main outcome variables

Investigating the amount of liver enzymes; Renal enzymes; Blood lactate; Diuresis; Bleeding rate; Taking inotropic drugs; Long stay at the Intensive Care Unit(ICU)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200602047642N1**
Registration date: **2020-09-07, 1399/06/17**
Registration timing: **retrospective**

Last update: **2020-09-07, 1399/06/17**
Update count: **0**

Registration date

2020-09-07, 1399/06/17

Registrant information

Name

Neda Habibi

Name of organization / entity

Rajaei Cardiovascular Hospital, Tehran

Country

Iran (Islamic Republic of)

Phone

+98 86 3272 2458

Email address

neda.nahi@rhc.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-23, 1399/04/03

Expected recruitment end date

2020-08-24, 1399/06/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination and comparison of the effect of 30 and 70 pulses in pulsatile cardiopulmonary bypass on clinical outcome of patients undergoing Coronary Artery Bypass Graft (CABG) surgery

Public title

Clinical outcome of Pulsatile flow

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patient satisfaction to enter the study Patients in the age range of 40-65 years Elective patients are candidates for Coronary Artery Bypass Graft surgery Patients with ejection fraction above 30%

Exclusion criteria:

Having a history of heart surgery Having another processor with Coronary Artery Bypass Graft Liver failure as ALT> 40 units / l AST> 40 units / l Preoperative pulmonary function test in the form of FEV1 <65% Having a creatinine level above 2 mg/dl Having a hemoglobin level of less than 10 mg/dl

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of individuals to study groups (interventions and controls) was performed by randomized block method using 6 blocks. This was done with the relevant software by Master of Statistics. In each block there are 2 people related to the control group, 2 people related to the A intervention group and 2 people related to the B group, whose order was random and the blocks were selected using the table of random numbers.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are given explanations about the study and the three groups to be studied, and then they are asked to enter the study, but they are not told which group they are studying.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Rajaei Heart Hospital in Tehran

Street address

Shahid Rajaei Heart Hospital., Niayesh Intersection,Valiasr St

City

Tehran

Province

Tehran

Postal code

1995614331

Approval date

2020-01-25, 1398/11/05

Ethics committee reference number

IR.RHC.REC.1398.084

Health conditions studied

1

Description of health condition studied

Atherosclerotic heart disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

Liver enzymes

Timepoint

Before, 24 and 48 hours after the operation

Method of measurement

Lab kits

2

Description

Renal enzymes

Timepoint

Before, 24 and 48 hours after the operation

Method of measurement

Lab kits

3

Description
Blood lactate
Timepoint
Before, 24 and 48 hours after the operation
Method of measurement
Lab kits

4

Description
Urine
Timepoint
Before the pump, during the pump, 12 and 24 hours after the operation
Method of measurement
Urine bag

5

Description
Bleeding
Timepoint
12 and 24 hours after the operation
Method of measurement
Chest tube

6

Description
Inotropic consumption
Timepoint
12 and 24 hours after the operation
Method of measurement
Yes/No

7

Description
Long stay at the intensive care unit
Timepoint
In the intensive care unit
Method of measurement
Hours recorded in the patient's file

8

Description
The duration of the intubation
Timepoint
In the intensive care unit
Method of measurement
Hours recorded in the file

Secondary outcomes

1

Description
Consumption of blood and blood products
Timepoint
In the operating room and Intensive care unit
Method of measurement
Each unit of product consumed

Intervention groups

1

Description
First intervention group: In the heart and lung pump machine, the pulse flow settings are as follows: Pulse number: 30, base flute: 30%, pulse width: 40%. After the pump starts and immediately after the aortic clamp, the pulsating current will start, and after removing the clamp, the aorta will end and the pump will continue with the continuous flow.
Category
Other

2

Description
Second intervention group: In the heart and lung pump machine, the pulse flow settings are as follows: Pulse number: 70, base flute: 30%, pulse width: 40%. After the pump starts and immediately after the aortic clamp, the pulsating current will start and after removing the clamp the aorta will end and the pump will continue with the continuous flow.
Category
Other

3

Description
Control group: Patients in this group are only subjected to a continuous flow, which by default is set in the pump machine, and no other adjustments are made.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaei Heart Hospital, Tehran
Full name of responsible person
Neda Habibi
Street address
Shahid Rajaei Heart Hospital, Niayesh Intersection, Valiasr St
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behsan@rhc.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Rajaei Heart Hospital, Tehran
Full name of responsible person
Dr. Majid Maleki
Street address
Shahid Rajaei Heart Hospital ., Niayesh Intersection, Valiasr St
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behsan@rhc.ac.ir
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Rajaei Heart Hospital, Tehran
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
Rajaei Cardiovascular Hospital, Tehran
Full name of responsible person
Neda Habibi
Position
Student of Perfusion
Latest degree
Bachelor
Other areas of specialty/work
Anesthesiology
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Shahid Rajaei Heart Hospital , Niayesh Intersection,Valiasr St
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Person responsible for updating data

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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