

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Clinical trial comparing blood flow pulsating heart pumps to assist patients with non-pulsating flow of blood pumped during the patient's kidney function in the proximal graft surgery, coronary artery bypass grafting

Protocol summary

Summary

Objectives: Given the limited studies that have been conducted regarding the pulsating heart. We decided to investigate the impact pulsating blood flow pump to help heart patients on renal function in the proximal graft during surgery, coronary artery bypass grafting in Baqiyatallah Hospital. Design: This is a triple-blind, randomized clinical trial. Setting and conduct: This study will perform at the Baqiyatallah University of Medical Sciences. Patients in both groups will divide randomly using a table of random numbers. Count of Bacteria is another outcome in this study and assess using the laboratory. This clinical trial is a phase 2 study. Major Inclusion and Exclusion criteria: patients referred for coronary artery bypass grafting after obtaining informed consent. Emergency patients, obese BMI greater than 40, has a history of heart surgery, a history of liver disease and impaired liver function tests and patients with insulin-dependent diabetes, kidney disease or high creatinine are excluded. Intervention: 36 patients using pulsating blood flow pump to help heart rate and blood flow in 36 patients with non-pulsating pump will be evaluated. During the intervention the proximal graft in coronary artery bypass grafting done. Main outcome measures (variables): Variables kidney function, including creatinine and blood urea nitrogen (B.U.N).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102230421N1**
Registration date: **2017-05-15, 1396/02/25**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-15, 1396/02/25

Registrant information

Name

Marzieh Lak

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

marziehlak@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Baqiyatallah University of Medical Sciences

Expected recruitment start date

2015-04-24, 1394/02/04

Expected recruitment end date

2016-04-29, 1395/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparing blood flow pulsating heart pumps to assist patients with non-pulsating flow of blood pumped during the patient's kidney function in the proximal graft surgery, coronary artery bypass grafting

Public title

Effect of pulsatile blood flow pumps to help heart patients on renal function during surgery graft proximal coronary artery bypass grafting

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients referred for coronary artery bypass grafting after obtaining informed consent
Exclusion criteria were included: emergency patients, obese BMI greater than 40, has a history of heart surgery, a history of liver disease and impaired liver function tests and patients with insulin-dependent diabetes, kidney disease or high creatinine are excluded.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 72

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiyatallah University of Medical Sciences

Street address

Postal code: 1435917541, Mollasadra, St - Sheikh Bahaee, St, Tehran

City

Tehran

Postal code

1435917541

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

ir.bmsu.rec.1394.171

Health conditions studied

1

Description of health condition studied

Atherosclerotic heart disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes

1

Description

Inotrope

Timepoint

After intervention in ICU, one and two days after intervention

Method of measurement

Clinical

2

Description

Creatinine

Timepoint

After intervention in ICU, one and two days after intervention

Method of measurement

Laboratory

Secondary outcomes

1

Description

Blood urea nitrogen (BUN)

Timepoint

After intervention in ICU, one and two days after intervention

Method of measurement

Laboratory

Intervention groups

1

Description

Intervention group: With about a third of tidal volume ventilation began air volume. When the heart begins to beat with HR greater than 60 and the regular rhythm of heart through a partial obstruction in the tube by tube clump Back venous pumping action of the heart have to fill out so that the Rtrialn monitor pulse rate were observed.

Category

Treatment - Surgery

2

Description

Control group: routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Surgery Department of Baqiyatallah hospital

Full name of responsible person

Marzieh Lak

Street address

Postal code: 1435917541, Mollasadra Street, Sheikh
Bahaee St, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Baqiyatallah University
of Medical Sciences

Full name of responsible person

Hamid Reza Rasouli

Street address

Postal code: 1435917541, Mollasadra Street, Sheikh
Bahaee Street, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Baqiyatallah University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Baqiyatallah University of Medical Sciences

Full name of responsible person

Marzieh Lak

Position

Faculty member/Anesthesiologist

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty