Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of effect of 1:1 and 1:2 frequency of Intra-aortic balloon pump on hemodynamic situation in patients with medium dose of inotrope after Coronary Artery Bypass Graft

Protocol summary

Study aim
Comparison of effect of 1:1 and 1:2 frequency of Intra-aortic balloon pump on hemodynamic situation in patients with medium dose of inotrope after Coronary Artery Bypass Graft

Design
quasi-experimental , with pretest - post test, no blinding,

Settings and conduct
Cases are patients who need Intra-aortic balloon pump after coronary artery bypass graft in Isfahan Chamran Heart Hospital, the device is set to 1: 1 frequency and it changes to 1:2 frequency for 20 minutes after reaching a median dose of inotropes, then cardiac parameters are recorded at two frequencies by echocardiography.

Participants/Inclusion and exclusion criteria
Entry Conditions: People who underwent CABG but due to low cardiac output, mean arterial blood pressure less than 80 mmHg failed to separate from the cardiopulmonary pump device and required postoperative IABP. Patients who are consenting to participate in the project, which will be obtained from the legal guardian if the patient is unconscious. Non-Entry Conditions: People performing CABG at the same time as aortic valve and arch-related operations such as: aortic valve replacement, Bental surgery, etc.

Intervention groups
This design is a quasi-experimental study of pre-test - posttest that compares all those who were at the 1: 1 frequency before and at the start of the intervention with the 1: 2 frequency step.

Main outcome variables
Cardiac index; Cardiac output; Systolic blood pressure; Diastolic blood pressure; Arterial mean pressure; Heart rate; Integrated aortic blood flow at diastolic time

General information

Reason for update

Acronym
IABP

IRCT registration information
IRCT registration number: **IRCT20190922044844N1**
Registration date: **2020-03-03, 1398/12/13**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-03, 1398/12/13**
Update count: **0**

Registration date
2020-03-03, 1398/12/13

Registrant information

Name
Moniresadat Afzali arani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7753 1154

Email address
m.afzali@resident.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-07, 1398/07/15

Expected recruitment end date
2020-05-20, 1399/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of effect of 1:1 and 1:2 frequency of Intra-aortic balloon pump on hemodynamic situation in patients with medium dose of inotrope after Coronary Artery Bypass Graft

Public title
Comparison of effect of two different frequencies of Intra-aortic balloon pump on hemodynamic situation in patients after Coronary Artery Bypass Graft

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People who underwent CABG but due to low cardiac output, mean arterial blood pressure less than 80 mmHg failed to separate from the cardiopulmonary pump device and required postoperative IABP. Patients who are consenting to participate in the project, which will be obtained from the legal guardian if the patient is unconscious.

Exclusion criteria:
People who perform CABG at the same time as aortic valve and arch operations such as: aortic valve replacement, Bental surgery, etc.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **9**
More than 1 sample in each individual
Number of samples in each individual: **2**
The hemodynamic parameters defined in the article are first measured in patients with a 1: 1 frequency of the intra-aortic balloon pump and then re-measured in the phase when patients are at a 1: 2 frequency.

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Unit 24, No. 73, Hoquqi Ave., Somayeh Cross., Shariaty Ave.

City
Tehran

Province
Tehran

Postal code
1611812345

Approval date
2019-07-28, 1398/05/06

Ethics committee reference number
IR.MUI.MED.REC.1398.229

Health conditions studied

1

Description of health condition studied
Influence of 1: 1 and 1: 2 frequency balloon pumps

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The rate of change in the velocity time integral of aortic blood flow during systole

Timepoint
In average dose of Inotropes, this parameter is measured at 1:1 frequency,then the frequency is switched to 1:2 and after 20 minutes, it's measured at 1:2 frequency again.

Method of measurement
The velocity time integral value of aortic blood flow during systole is measured by echocardiography.

2

Description
The measurement of area left ventricular outflow tract (area LVOT)

Timepoint
At moderate doses of inotropic drugs, this variable is measured before the intervention begins.

Method of measurement
This variable is measured by echocardiography,

3

Description
Rate of change in systolic blood pressure in patients

Timepoint
In average dose of Inotropes, this parameter is measured at 1:1 frequency,then the frequency is switched to 1:2

and after 20 minutes, it's measured at 1:2 frequency again.

Method of measurement

it's measured by a built-in arterial line for patients and cardiac monitoring devise

4

Description

Rate of change in diastolic blood pressure in patients

Timepoint

In average dose of Inotropes, this parameter is measured at 1:1 frequency,then the frequency is switched to 1:2 and after 20 minutes, it's measured at 1:2 frequency again.

Method of measurement

it's measured by a built-in arterial line for patients and cardiac monitoring devise

5

Description

Rate of change in heart rates in patients

Timepoint

In average dose of Inotropes, this parameter is measured at 1:1 frequency,then the frequency is switched to 1:2 and after 20 minutes, it's measured at 1:2 frequency again.

Method of measurement

it's measured by a cardiac monitoring devise

6

Description

Rate of change in mean arterial blood pressure in patients

Timepoint

In average dose of Inotropes, this parameter is measured at 1:1 frequency,then the frequency is switched to 1:2 and after 20 minutes, it's measured at 1:2 frequency again.

Method of measurement

it's measured by a built-in arterial line for patients and cardiac monitoring devise

7

Description

The measure of body surface area

Timepoint

At moderate doses of inotropic drugs, this variable is measured before the intervention begins.

Method of measurement

This variable is measured by echocardiography,

8

Description

Rate of change in cardiac output of patients

Timepoint

In average dose of Inotropes, this parameter is measured at 1:1 frequency,then the frequency is switched to 1:2 and after 20 minutes, it's measured at 1:2 frequency again.

Method of measurement

It will be calculated by the formula and collected required data

9

Description

Rate of change in cardiac index of patients

Timepoint

In average dose of Inotropes, this parameter is measured at 1:1 frequency,then the frequency is switched to 1:2 and after 20 minutes, it's measured at 1:2 frequency again.

Method of measurement

It will be calculated by the formula(cardiac output divided by body surface area) and collected required data

Secondary outcomes

empty

Intervention groups

1

Description

This design is a quasi-experimental study of pre-test - posttest that compares all those who were at the 1: 1 frequency before and at the start of the intervention with the 1: 2 frequency step.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan shahid chamran hospital

Full name of responsible person

Amir Mirmohammadsadeghy

Street address

Shahid chamran Hospital, After city bridge, Third Ave, Bozorgmehr Square

City

Isfahan

Province

Isfehan

Postal code

۸۱۵۸۳۸۸۹۹۴

Phone

+98 31 3303 3710

Email

am_sadeghi@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Amir Mirmohammadsadeghy

Street address
Isfahan University of Medical Sciences and Health Services, Hezar Jerib Ave, Azadi Square.

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3668 0048

Email
am_sadeghi@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Amir mirmohammadsadeghy

Position
Assistant Professor of Medical School

Latest degree
Subspecialist

Other areas of specialty/work
Cardiology

Street address
Beginning of the Tower Garden 1, Corner of the Tower, Nizwan, Isfahan

City
Isfahan

Province
Isfehan

Postal code
1611812345

Phone
+98 31 3773 3390

Email
am_sadeghi@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Amir mirmohammadsadeghy

Position
Assistant Professor of Medical School

Latest degree
Subspecialist

Other areas of specialty/work
Cardiology

Street address
Beginning of the Tower Garden 1, Corner of the Tower, Nizwan, Isfahan

City
Isfahan

Province
Isfehan

Postal code
1611812345

Phone
+98 31 3773 3390

Email
am_sadeghi@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Amir mirmohammadsadeghy

Position
Assistant Professor of Medical School

Latest degree
Subspecialist

Other areas of specialty/work
Cardiology

Street address
Beginning of the Tower Garden 1, Corner of the Tower, Nizwan, Isfahan

City
Isfahan

Province
Isfehan

Postal code
1611812345

Phone
+98 31 3773 3390

Email
am_sadeghi@med.mui.ac.ir

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