

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effect of preconditioning of sevofluran in coronary artery bypass surgery

Protocol summary

Summary

Objective: Decrease inotrope uses to exit the bypass pump; Reduce the incidence of transient cardiac ischemia after surgery; Reduce ICU staying. Design: Randomized single-blind clinical trial. Setting and conduct and intervention: In all patient induction (sufentanil, cis-atracurium and etomidate) and maintenance phase (sufentanil, midazolam, cis-atracurium) of anesthesia will be considered with the same protocol. After cross-clamp of aorta in intervention group, the patient will receive oxygen (2 Lit/min) and sevofluran (4%) during coronary bypass surgery. After rewarming of the patients, sevofluran will be omitted. Inclusion criteria: All elective coronary bypass surgery in patients 40 to 80 years old. Exclusion criteria: AV block (Mobitz 2); complete Heart block; LBBB; Acute heart failure (EF < 30); Reexploration after surgical complications; MI in last 7 days ago. Main outcome measures (variables): The effect of sevofluran on preconditioning of heart during CABG will be evaluated with checking troponin and heart nuclear scan.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061528477N1**

Registration date: **2016-08-02, 1395/05/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-02, 1395/05/12

Registrant information

Name

Sina Ofoghie Rezaei

Name of organization / entity

Bushehr University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3336 3930

Email address

s.ofoghirezaei@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Bushehr University of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of preconditioning of sevofluran in coronary artery bypass surgery

Public title

The effect of preconditioning of sevofluran in cardiac ischemia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All elective coronary bypass surgery in patients 40 to 80 years old. Exclusion criteria: AV block (Mobitz 2); complete Heart block; LBBB; Acute heart failure (EF < 30); Reexploration after surgical complications; MI in last 7 days ago.

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

sampling: simple randomize

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Boushehr Medical Sciences University

Street address

Boushehr Medical Sciences University, Sangi, Boushehr

City

Boushehr

Postal code

Approval date

2016-05-16, 1395/02/27

Ethics committee reference number

IR.BPUMS.REC.1395.23

Health conditions studied

1

Description of health condition studied

Preconditioning of heart during coronary artery bypass surgery

ICD-10 code

T82.9

ICD-10 code description

Unspecified complication of cardiac and vascular prosthetic device, implant and graft

Primary outcomes

1

Description

Troponin I blood level

Timepoint

At entrance to ICU and after 4,8,24,48 hours from coronary bypass surgery

Method of measurement

µg/10.01 SI unit

2

Description

Electrocardiography

Timepoint

ECG changes at entrance to ICU and daily up to 4 days.

Method of measurement

Electrocardiography device

3

Description

Nuclear heart scan

Timepoint

3 nuclear heart scan before CABG and 1 and 6 month after surgery.

Method of measurement

SPECT-CT Scan

Secondary outcomes

1

Description

Systolic blood pressure

Timepoint

Before anesthesia induction, one minute after off pump, one hour after off pump, 8 and 24 hour after surgery

Method of measurement

Heart Monitoring

2

Description

Diastolic blood pressure

Timepoint

Before anesthesia induction, one minute after off pump, one hour after off pump, 8 and 24 hour after surgery.

Method of measurement

Heart Monitoring

3

Description

Mean arterial pressure

Timepoint

Before anesthesia induction, one minute after off pump, one hour after off pump, 8 and 24 hour after surgery.

Method of measurement

Heart Monitoring

4

Description

Heart rate

Timepoint

Before anesthesia induction, one minute after off pump, one hour after off pump, 8 and 24 hour after surgery.

Method of measurement

Heart Monitoring

Intervention groups

1

Description

Intervention: after induction of anesthesia in intervention group, the patient will receive oxygen (2Lit/min) and sevofluran(4%) during coronary bypass surgery.

Category

Treatment - Drugs

2

Description

Control: after induction of anesthesia in control group, the patient will receive oxygen(2Lit/min).

Category

Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Cardiac Center of Boushehr

Full name of responsible person

Dr.Anvaripour

Street address

Cardiac Center of Boushehr

City

Boushehr

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Boushehr Medical Scinces University

Full name of responsible person

Afshin Ostovar

Street address

Bushehr Medical Scinces University,Sanggi,Bushehr

City

Boushehr

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Boushehr Medical Scinces University

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**

Boushehr Medical Scinces University

Full name of responsible person

Dr.Anvaripour

Position

Anesthesia Department Assisstance

Other areas of specialty/work**Street address**

Boushehr Cardiac Center

City

Boushehr

Postal code**Phone**

+98 77 3345 0178

Fax**Email**

sina_rezaei_70@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Boushehr Medical Scinces University

Full name of responsible person

Dr.Anvaripour

Position

Anesthesia Department Assisstance

Other areas of specialty/work**Street address**

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Person responsible for updating data

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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