

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Investigating the Pulmonary Function Parameters following Coronary Artery Bypass Surgery in Patients with General Anesthesia and General Anesthesia with Spinal Anesthesia

Protocol summary

Study aim

Investigating the pulmonary function parameters following coronary artery bypass surgery in patients with general anesthesia and general anesthesia with spinal anesthesia.

Design

Patients are randomly divided into intervention and control groups and the study design is a randomized, controlled, parallel-group trial with double blinded outcome assessment. Randomization is centralized based on simple randomization method using random digits table. phase 3, sample size 60

Settings and conduct

Sixty patients candidate of coronary artery bypass surgery in age group 40 to 65 years in Ahvaz Imam Khomeini hospital are studied into intervention and control group (n=30). Participants, researchers responsible for data collection and analyses are blind to the groups allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria are male patients who are candidates for coronary artery bypass surgery in age group 40 to 65 years; The exclusion criteria are patients with history of cardiac surgery, history of coagulopathy, antiplatelet consumption before surgery, severe lumbar deformity or BMI greater than 35, contraindication of neuro-axial block and systemic or local infection.

Intervention groups

In control group, general anesthesia is administered intravenously with midazolam 2 mg, fentanyl 3 µg/kg, lidocaine (20%) 1.5 mg/kg, thiopental sodium 3 mg/kg and atracurium 0.6 mg/kg and in the intervention group, before induction of general anesthesia, spinal anesthesia is performed with intrathecal injection of 20 mg bupivacaine 0.5% on sitting position in L3-L4 midline space with needle gauge 25.

Main outcome variables

Tidal volume, vital capacity, the partial pressure of oxygen and carbon dioxide and blood PH in 1, 2, 4, 6 and 12 hours after extubation are measured.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191016045133N1**

Registration date: **2019-11-08, 1398/08/17**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-08, 1398/08/17**

Update count: **0**

Registration date

2019-11-08, 1398/08/17

Registrant information

Name

Sina Dehdashti

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-15, 1398/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Pulmonary Function Parameters following Coronary Artery Bypass Surgery in Patients with General Anesthesia and General Anesthesia with Spinal Anesthesia

Public title

Investigating the Pulmonary Function Parameters following Coronary Artery Bypass Surgery in Patients with General Anesthesia and General Anesthesia with Spinal Anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Male patients who are candidates for coronary artery bypass surgery Age group 40 to 65 years

Exclusion criteria:

History of cardiac surgery History of coagulopathy Antiplatelet consumption before surgery Severe lumbar deformity or BMI greater than 35 Contraindication of neuro-axial block Systemic or local infection

Age

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

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are randomly divided into two groups based on simple randomization method using random digits table. In this method, a collection of non-template numbers is randomly generated and arranged as a table. Even numbers for the intervention group and the odd numbers for the control group are considered. According to the number of patients, they are randomly assigned to one of the intervention or control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants are informed about the purpose and method of study. After receiving informed consent, they are blinded to the study groups to unify patients in terms of their induction sense. Researchers responsible for data collection and analyses are also blind to the groups allocation.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz University of Medical Sciences

Street address

Research deputy, Ahvaz Jundishapur University Of Medical Sciences, Golestan Blvd.

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Khouzestan

Postal code

6135715794

Approval date

2019-04-13, 1398/01/24

Ethics committee reference number

IR.AJUMS.REC.1398.005

Health conditions studied**1****Description of health condition studied**

coronary artery bypass

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Tidal Volume (TV)

Timepoint

1, 2, 4, 6 and 12 hours after extubation

Method of measurement

Spirometry

2**Description**

Vital Capacity (VC)

Timepoint

1, 2, 4, 6 and 12 hours after extubation

Method of measurement

The sum of Tidal Volume (TV) and Inspiratory Reserve Volume (I.R.V) and Expiratory Reserve Volume (E.R.V) (Using spirometry)

3

Description

The partial pressure of carbon dioxide (PaCO₂)

Timepoint

1, 2, 4, 6 and 12 hours after extubation

Method of measurement

Blood test

4

Description

The partial pressure of oxygen (PaO₂)

Timepoint

1, 2, 4, 6 and 12 hours after extubation

Method of measurement

Blood test

5

Description

Blood PH

Timepoint

1, 2, 4, 6 and 12 hours after extubation

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Control group: General anesthesia is administered intravenously with midazolam 2 mg, fentanyl 3 µg/kg, lidocaine (20%) 1.5 mg/kg, thiopental sodium 3 mg/kg and atracurium 0.6 mg/kg.

Category

Treatment - Drugs

2

Description

Intervention group: Before induction of general anesthesia, spinal anesthesia is performed with intrathecal injection of 20 mg bupivacaine 0.5% on sitting position in L3-L4 midline space with needle gauge 25.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Imam Khomeini Hospital, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Kamaladin Tabatabaei

Street address

Imam Khomeini Hospital, Azadegan Ave.

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi, PhD

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

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Sina Dehdashtiha

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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

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Assistant professor

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Specialist

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Cardiac anesthesia fellowship

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

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Other areas of specialty/work

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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

Not applicable

Data Dictionary

Not applicable