Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Aug 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

Iran (Islamic Republic of)

Phone

+98 61 3292 3589

Email address

dehdashti.s@ajums.ac.ir

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.
City
Ahvaz
Province
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.
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3222 2925
Email
KT1343@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi, PhD
Street address
Deputy of Research, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8383
Email
info@ajums.ac.ir
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
Street address
Imam Khomeini Hospital, Azadegan Ave.
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
009861329235893
Email
Sina.dehdashti@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Kamaladin Tabatabaei
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Cardiac anesthesia fellowship
Street address
Imam Khomeini Hospital, Azadegan Ave.
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
009861322235292
Email
KT1343@gmail.com

Person responsible for updating data

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
Street address
Imam Khomeini Hospital, Azadegan Ave.
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
009861329235893
Email
Sina.dehdashti@gmail.com

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