Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the dead space/tidal volume in intravenous anesthesia and inhaled anesthesia in morbid obesity undergoing bariatic surgery

Protocol summary

Study aim
Comparison of ventilation prognosis and respiratory problems in two methods of intravenous and inhalation anesthesia
Design
Clinical trial without control group, parallel groups, double blind, randomized with 60 patients
Settings and conduct
Patients undergoing bariatric surgery at Rasool Akram hospital are randomly assigned to two groups. Participants and outcome assessor will also not be aware of the intervention types.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 17 to 50 years, Not having co-morbidity disease, No smoking, No alcohol consumption, BMI>40 and Duration of surgery less than 4 hours, consent to participate the study. Exclusion criteria: Having chronic obstructive pulmonary disease (COPD), having intestines adhesion
Intervention groups
Group 1: Intravenous Anesthesia, Group 2: Inhaled Anesthesia
Main outcome variables
Dead space/tidal volume ratio (VD/VT)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180723040570N4**
Registration date: **2020-01-30, 1398/11/10**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-30, 1398/11/10**
Update count: **0**
Registration date
2020-01-30, 1398/11/10

Registrant information
Name
Nasim Nikoubakht
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 8862 9854
Email address
nikoobakht.n@iums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-01-05, 1398/10/15
Expected recruitment end date
2021-01-04, 1399/10/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the dead space/tidal volume in intravenous anesthesia and inhaled anesthesia in morbid obesity undergoing bariatic surgery

Public title
Difference of the dead space/tidal volume in intravenous anesthesia and inhaled anesthesia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 17 to 50 years BMI>40 Duration of surgery less than 4 hours Consent to participate in the study
Exclusion criteria:
Having chronic obstructive pulmonary disease (COPD)

Having intestines adhesion Smoking Alcohol consumption

Age
From **17 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients were randomly divided into intervention and control groups using a lottery method. As the names of all participants are placed inside the container. The names are drawn out from the container, respectively, and placed in the intervention and control groups. At the end, the papers containing the names are opened and different groups are determined.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and outcome assessor will not aware of the intervention because patients are unable to detect the type of anesthesia after anesthesia, and a vein line is established for both groups. The outcome assessor (in the recovery room) is unaware of the allocation of groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Next to Milad Tower, Hemat Highway ,Tehran

City
تهران

Province
Tehran

Postal code
14496-14535

Approval date
2019-04-07, 1398/01/18

Ethics committee reference number
IR.IUMS.FMD.REC.1398.130

Health conditions studied

1

Description of health condition studied
Bariatric surgery

ICD-10 code
Z98.84

ICD-10 code description
Bariatric surgery status

Primary outcomes

1

Description
Dead space to tidal volume ratio (VD/VT)

Timepoint
Before anesthesia and during anesthesia

Method of measurement
Ventilator monitor

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Intravenous Anesthesia. In this group, premedication with 0.05 mg / kg midazolam and 3 mcg / kg fentanyl and induction with 5mg / kg thiopental and 0.3 mg / kg cisatracurium will be performed. Also, the maintenance will be done with 100 mcg / kg propofol.

Category
Treatment - Surgery

2

Description
Intervention group 2: Inhaled anesthesia. In this group, premedication with 0.05 mg / kg midazolam and 3 mcg / kg fentanyl and induction with 5mg / kg thiopental and 0.3 mg / kg cisatracurium will be performed. Also, the maintenance will be done with one minimum alveolar concentration (MAC).

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasoul Akram hospital

Full name of responsible person
Nasim Nikoobakht
Street address
Satarkhan St,Tehran, Tehran Province
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 1000
Email
nnikobakht@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyad Abbas Motavalian
Street address
Hemat ave.Iranuniversity of medical sciences
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 1000
Email
amotevalian@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Nasim Nikoobakht
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Hemat ave.Iranuniversity of medical sciences
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 1000
Email
nnikobakht@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Nasim Nikoobakht
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Hemat ave.Iranuniversity of medical sciences
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 1000
Email
nnikobakht@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Nasim Nikoubakht
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Rasool Akram, Maziar Mansory Ave, Satarkhan Ave.
City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 64351

Email

Nikoobakht.n@iums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

All individual data of the participants in this study will be shared after unidentifiable individuals

When the data will become available and for how long

The access period will start from 2020 to 2022

To whom data/document is available

Data will be available to researchers working in the university

Under which criteria data/document could be used

Scientific responsible should be received email request for research purposes. Of course, the email must be sent by an academic email.

From where data/document is obtainable

To access the data, forward email to nnikobakht@yahoo.com

What processes are involved for a request to access data/document

The data will be available one month after the responsible person's approval

Comments