

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 bariatric 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 bariatric 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 Nikoobakht
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