

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparison ventilation quality by anatomic or nasal mask after induction of general anesthesia in patients with body mass index more than 40

Protocol summary

Study aim

Comparison of ventilation quality after induction of anesthesia by using two methods of Anatomic Face Mask or Nasal Anatomical Mask in subjects with BMI more than 40

Design

70 patients undergoing surgery with general anesthesia will be divided into two groups. In the first group, ventilation with 100% oxygen is performed for three minutes by anatomical face mask. In the second group, ventilation is done through the anatomical nasal mask.

Settings and conduct

This single-blind clinical trial study was performed in Alzahra Hospital in Isfahan, Iran, during 2019-20. 70 patients were randomly divided into two groups of 35 each, in the first group ventilation with face mask and in the second group with nasal mask and the quality of ventilation was compared in two groups. In this study, mask implementations are performed by the researcher and data collection will be done by another person who is not in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients undergoing elective surgery under general anesthesia. Non inclusion criteria: Patients with obstruction of the nose, clear deformity, or fracture in the case of either acute or chronic pulmonary disease.

Intervention groups

Intervention group 1: ventilation is done by face mask.
Intervention group 2: ventilation is done by nasal mask.

Main outcome variables

Volume of sequential exhaustion; Oxygen saturation percentage; Maximum airway pressure; Heart Beat; Systolic blood pressure; Diastolic blood pressure; Mean blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N37**

Registration date: **2019-11-13, 1398/08/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-13, 1398/08/22**

Update count: **0**

Registration date

2019-11-13, 1398/08/22

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-22, 1398/06/31

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison ventilation quality by anatomic or nasal mask after induction of general anesthesia in patients with body mass index more than 40

Public title

Comparison of two methods of face or nasal mask in fat patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Body Mas Index above 40 kg/m2 Age range between 18-70 years old Candidate for elective surgery under general anesthesia

Exclusion criteria:

Nasal Obstruction Clear deformity or fracture of the face Acute or chronic Pulmonary disease

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

1

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly divided into two intervention 1 and intervention 2 groups by using Random Allocation Software.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the face or nasal mask is embedded by the researcher and the data is collected by another person who is not aware of the process of the study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Isfahan University of Medical Sciences

Street address

Department of Anesthesiology, Alzahra hospital, Soffeh street

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8434193474

Approval date

2017-05-30, 1396/03/09

Ethics committee reference number

IR.MUI.REC.1396.3.304

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

Mechanical Ventilation

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

Sequential expiratory tidal volume

Timepoint

2 and 5 minutes after incubation

Method of measurement

Pulse oximeter

2**Description**

Percentage of blood Oxygen Saturation

Timepoint

2 and 5 minutes after incubation

Method of measurement

Pulse oximeter

3**Description**

Systolic Blood Pressure

Timepoint

2 and 5 minutes after incubation

Method of measurement

Pulse oximeter

4**Description**

Diastolic Blood Pressure

Timepoint

2 and 5 minutes after incubation

Method of measurement

Pulse Oximeter

5**Description**

Heart rate

Timepoint

2 and 5 minutes after incubation

Method of measurement

Pulse oximeter

6

Description

Mean Arterial Blood Pressure

Timepoint

2 and 5 minutes after incubation

Method of measurement

Pulse oximeter

Secondary outcomes

1

Description

Unability to do ventilation during masking

Timepoint

At the first to 5 minutes of intubation

Method of measurement

Observation

Intervention groups

1

Description

Intervention group 1: In this group, routine ventilation with anatomical face mask and 100% oxygen is performed for three minutes. Ventilation is performed using anesthesia control mode at a volume of 8 cc / kg and speed of 12 min. The mean expiratory tidal volume, mean of SpO₂, mean of EtCO₂, mean of maximum air way pressure in three consecutive breaths in the second minute after the start of ventilation will be determined and recorded.

Category

Treatment - Devices

2

Description

Intervention group2: In this group ventilation is done through the nasal mask. Ventilation is performed using anesthesia control mode at a volume of 8 cc / kg and speed of 12 min. The mean expiratory flow volume, SpO₂ mean, EtCO₂ mean, mean maximal airway pressure were measured and recorded in the second minute after the start of ventilation.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Hamid Saryazdi

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Department of Anesthesiology, Alzahra hospital, Sofeh street, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Sajjad Adib

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Specialist

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Because the project is owned by the university, it is not possible to publish its data.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available