Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 2026

A comparative study of face mask ventilation quality of two different mask holding techniques: three finger grip with and without sub-mental maneuver, in infants (0-1 year of age) under general inhalation anesthesia

Protocol summary

Study aim

Compare ventilation quality of two different mask holding techniques (three finger grip with and without submental maneuver) in infants (<1 y/o)

Design

A double-blind randomized controlled trial with a parallel group design on 90 patients

Settings and conduct

This is an interventional study of infants undergoing elective surgery with general anesthesia in Children's Medical Center. After obtaining written informed consent from the guardians of the infants, patients are allocated to one of the interventional groups randomly, using the randomization.com website. After connecting the standard monitoring devices, general anesthesia is induced with 8% sevoflurane and 100% oxygen (flow=2lit/min) using one of the mask holding techniques (three finger grip with/without submental maneuver) in neutral position before intubation. Demographic data (age, sex, weight and height) for each patient is collected. Quantitative hemodynamic parameters (blood pressure, pulse rate & O2 saturation), expiratory tidal volume (quality of the patient's breath flow to the hyperinflation bag), abnormal respiratory sounds and respiratory distress are evaluated by a single experienced anesthesiologist and recorded by a third person unaware of the patient's group, during mask ventilation. End-tidal CO2 pressure is measured immediately after intubation. In case of any unexpected event, the necessary actions will be taken.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Infants; ASA 1, 2; elective surgery; general anesthesia Exclusion Criteria: history of respiratory disease; maxillofacial anomalies; chest wall deformity; any object interfering with mask ventilation

Intervention groups

Group 1: three finger grip Group 2: three finger grip with submental maneuver

Main outcome variables

Expiratory tidal volume; End-tidal CO2 pressure; O2 sat; SBP and DBP; PR; Respiratory sounds and respiratory distress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221114056498N1**
Registration date: **2022-12-18, 1401/09/27**
Registration timing: **prospective**

Last update: **2022-12-18, 1401/09/27**
Update count: **0**

Registration date

2022-12-18, 1401/09/27

Registrant information

Name
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of face mask ventilation quality of two different mask holding techniques: three finger grip with and without sub-mental maneuver, in infants (0-1 year of age) under general inhalation anesthesia

Public title

Adding submental maneuver to three finger mask holding technique in general inhalation anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age under 1 year old ASA 1, 2 Candidate for elective surgery Undergoing general anesthesia

Exclusion criteria:

Presence of any maxillofacial anomalies Chest wall deformity Any past medical history of respiratory diseases Any foreign object interfering with mask ventilation

Age

To **12 months** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The required sample size for this study is 90. Subjects were randomized into 2 blocks using the website www.randomization.com before beginning the investigation. 45 numbers out of the numbers 1-90 were allocated randomly to each intervention group (group 1: three finger grip without the submental maneuver, group 2: three finger grip with the submental maneuver). The number and its assigned technique were inserted in the data collection form for each patient. For example, it was specified that, for patient number 4 the threff finger grip technique without the submental maneuver should be performed. Only the researcher performing mask ventilation is aware of the patient's allocated group. The person in charge of collecting the data is unaware of the patient's group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Parents/guardians of the infant from whom written informed consent was obtained were unaware of the allocated group of the patient. Only the researcher performing mask ventilation was aware of the technique used for mask ventilation in each patient. Also, the monitor showing the parameters that were intended to be studied in this study and the hyperinflation bag were placed in a way that this researcher couldn't see them and was unaware of these parameters. The person collecting and writing the data from the monitor, not only was unaware of the mask holding technique for each patient, but also was positioned in a place that couldn't see the technique used by the researcher performing mask ventilation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Children's Medical Center-Tehran University of Medical Sciences

Street address

Dr. Qarib St.

City

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Province

Tehran

Postal code

1419733151

Approval date

2021-04-04, 1400/01/15

Ethics committee reference number

IR.TUMS.CHMC.REC.1400.024

Health conditions studied

1

Description of health condition studied

Face mask holding technique

ICD-10 code

T88.9

ICD-10 code description

Complication of surgical and medical care, unspecified

Primary outcomes

1

Description
expiratory tidal volume
Timepoint
During holding the mask
Method of measurement
Quality of patient's breath flow to the hyperinflation bag by an experienced anesthesiology attending (good-fair-bad)

Secondary outcomes

empty

Intervention groups

1

Description
Pulse oximeter and the right-sized blood pressure cuff are attached to the patient and the patient is monitored. Anesthesia machine is turned on and ready. Anesthesia is induced by 100 percent O2 and 8% sevoflurane gas, using the three finger grip technique without the submental maneuver before intubation.
Category
Treatment - Other

2

Description
Pulse oximeter and the right-sized blood pressure cuff are attached to the patient and the patient is monitored. Anesthesia machine is turned on and ready. Anesthesia is induced by 100 percent O2 and 8% sevoflurane gas, using the three finger grip technique with the submental maneuver before intubation.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Tehran 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
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Elahe Radmehr
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Intern
Latest degree
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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
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