

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

Elahe Radmehr

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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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 three 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
 Tehran
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

Children's Medical Center

Full name of responsible person

Elahe Radmehr

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Flat No. 3, No. 46, Shahid Taheri St., Nelson Mandella Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Room no. 605, Floor No. 6, Tehran University of Medical Sciences Main building, Qods St., Keshavarz Blvd.

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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

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Elahe Radmehr

Position

Intern

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Position

Intern

Latest degree

Medical doctor

Other areas of specialty/work

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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