

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the laryngoscopic view without the maneuver, Sellick's maneuver and Sellick's maneuver combined with the backward, upward, and rightward pressure on the larynx under general anesthesia during orotracheal intubation in pediatrics aged 2-8 years

Protocol summary

Summary

Objectives: This study is aimed to compare the laryngoscopic view without maneuver, Sellick's maneuver and Sellick's maneuver combined with the backward, upward, and rightward pressure on the larynx in patients under general anesthesia during orotracheal intubation in pediatrics aged 2-8 years. Design: Prospective crossover clinical trial. Setting and conduct: Tertiary regional and teaching hospital. Participants including major eligibility criteria: One hundred fifty patients candidate for general anesthesia and orotracheal intubation with ASA Class I- II, in Children Medical Center Hospital during 2011-2013, were included. Intervention: Each patient serving as his or her own control (without maneuver), Sellick's maneuver, and backward, upward, and rightward pressure. Main outcome measures (variables): Cormack and Lehane grading, Laryngoscopic view change. Type of maneuver are coded and delivered to the patients by individual not aware of the research process

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201303098435N3**

Registration date: **2013-03-13, 1391/12/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-03-13, 1391/12/23

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences and Health Services

Expected recruitment start date

2011-04-21, 1390/02/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the laryngoscopic view without the maneuver, Sellick's maneuver and Sellick's maneuver combined with the backward, upward, and rightward pressure on the larynx under general anesthesia during orotracheal intubation in pediatrics aged 2-8 years

Public title

Comparison of the laryngoscopic view with Sellick's maneuver and Sellick's maneuver combined with the backward, upward, and rightward pressure on the larynx

during orotracheal intubation patients under general anesthesia in pediatrics aged 2-8 years

Purpose

Prevention

Inclusion/Exclusion criteria

Main inclusion criteria: ASA Class I- II; signing consent to parents participate in the study Main exclusion criteria: Fracture or instability of the cervical spine; Active vomiting; Lesions of the trachea and cricoid; Foreign bodies in the upper airways; Emergency Surgery; History of difficult intubation or airway problems; Morbid obesity; Gastrointestinal obstruction or gastrointestinal disease; Renal failure, uremic, uncontrolled diabetes, and other conditions predisposing to aspiration; Trauma; Anomalies of the head and neck; Cleft lip and palate; Macroglossia

Age

From **2 years** old to **8 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Tehran University of Medical Sciences and Health Services

Street address

Poorsina Ave.

City

Tehran

Postal code

Approval date

2011-06-06, 1390/03/16

Ethics committee reference number

p/730

Health conditions studied

1

Description of health condition studied

Cormack and Lehane grade

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

View of laryngeal inlet

Timepoint

Before the maneuver, Sellick's maneuver, Sellick's maneuver combined with the backward, upward, and rightward pressure on the larynx

Method of measurement

Cormack & lehane grading

2

Description

change of laryngeal view

Timepoint

During sellick's maneuver and Sellick's maneuver combined with the backward, upward, and rightward pressure on the larynx

Method of measurement

Cormack & lehane grading

Secondary outcomes

empty

Intervention groups

1

Description

In the study group : Sellick's maneuver and Sellick's maneuver combined with the backward, upward, and rightward pressure on the larynx

Category

Prevention

2

Description

In the control group, Without the maneuver

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Children Medical Center- Hospital

Full name of responsible person

Alireza Ebrahim Soltani

Street address
Keshavarz Blvd, Gharib St.
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Tehran University of
Medical Sciences and Health Services
Full name of responsible person
Shahin Akhunzadeh MD.
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Poursina St.
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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

Vice chancellor for research, Tehran University of Medical
Sciences and Health Services

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty