Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 2026

Comparison of tracheal intubation with propofol - remifentanil and propofol – succynylcholine in children 3 -12 years

Protocol summary

Summary

Background and Objective: After induction of anesthesia, tracheal intubation is commonly facilitated by the use of muscle relaxants. Recent studies have suggested that propofol in combination with short-acting opioid such as alfentanil and remifentanil may provide adequate conditions for laryngoscopy and tracheal intubation without using muscle relaxants. In this study, we compare intubating conditions and cardiovascular changes following induction of anesthesia and tracheal intubation in patients receiving either propofol-remifentanil or propofol-succynylcholineto induction. Design: Single blind clinical trial. Setting: Patients were divided into two groups randomly: succynylcholin and remifentanil. Midazolam 0.05 mg.kg and lidocaine 1.5 mg.kg iv was given as premedication approximately 5 minutes before induction of anesthesia. All patients were prehydrated with ringer 5cc.kg before induction.Inclusion criteria: Sixty ASA 1 and2 children aged between 3 and 12 years who require tracheal intubation for elective surgery Exclusion Criteria: Children with common cold; cardiorespiratory disease; neuromascular disease; difficult intubation; other systemic disease Intervention:Control group, propofol(3 mg.kg) was first administrated ovrer10 s followed by succinylcoline(1.5mg.kg) as a rapid bolus. In study group, propofol was followed by remifentanil(2mic.kg) given as a slow blous infusion over 30 sec. Main outcomes: Intubation conditions were assessed as excellent, good or poor on the basis of jaw relaxation, vocal cords, bucking, coughing or body movements.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201209089874N2**
Registration date: **2013-08-11, 1392/05/20**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-08-11, 1392/05/20

Registrant information

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Babol University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice-chancellor Of Research Babol University Of Medical Science

Expected recruitment start date

2012-06-14, 1391/03/25

Expected recruitment end date

2013-03-15, 1391/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of tracheal intubation with propofol - remifentanil and propofol – succynylcholine in children 3 -12 years

Public title

Comparison of tracheal intubation with propofol - remifentanil and propofol – succynylcholine in children 3

-12 years

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion Criteria:Children aged between 3-12 who undergoing elective surgery. Exclusion Criteria:Children with common cold; cardiorespiratory disease; nuromuscular disease; difficult intubation; other systemic disease

Age

From **3 years** old to **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University Of Medical Sciences

Street address

Daneshgah Square, Ganjafrooz Avenue

City

Babol

Postal code

Approval date

2013-03-09, 1391/12/19

Ethics committee reference number

2159/30/ژ/پ

Health conditions studied

1

Description of health condition studied

General Anesthesia

ICD-10 code

T88.8

ICD-10 code description

Other complications of surgical and medical care, not elsewhere classified

Primary outcomes

1

Description

Determination of tracheal intubation condition in children without muscle relaxant with propofol-remifentanil

Timepoint

5 minutes before and after intubation

Method of measurement

Direct observation

Secondary outcomes

1

Description

Comparing pulse rate and blood pressure in two groups

Timepoint

5 minutes before and after intubation

Method of measurement

BP manometer, ECG

2

Description

Comparing laryngoscopy condition between two groups

Timepoint

During Laryngoscopy

Method of measurement

Direct observation

3

Description

Comparing cough between two groups

Timepoint

During and after intubation

Method of measurement

Direct observation

4

Description

Comparing movement of limbers between two groups

Timepoint

During and after intubation

Method of measurement

Direct observation

Intervention groups

1

Description

The intervention group, 3mg/kg propofol injection was used in 10 seconds, then 2microg/kg remifentanil injection is used in 30 seconds finally after 60 seconds,

laryngoscopy and intubation are performed.

Category

Diagnosis

2

Description

The control group, 3mg/kg propofol injection is used for 10 seconds, succynylcoline injection with 1.5mg/kg, after 50 seconds injected after 40 seconds, laryngoscopy and intubation are performed.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Ruhani Hospital

Full name of responsible person

Dr Freshteh Naziri

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Daneshgah Square, Ganjafrooz Avenue

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2

Recruitment center

Name of recruitment center

shahid Beheshti Hospital

Full name of responsible person

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shahid ghasemi Avenue

City

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3

Recruitment center

Name of recruitment center

Amirkola pediatric hospital

Full name of responsible person

Dr Freshteh Naziri

Street address

Emam Avenue

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor Of Research Babol University Of Medical Sciences

Full name of responsible person

Dr Amrolah Mostafazadeh

Street address

Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue

City

Babol

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-chancellor Of Research Babol University Of Medical Sciences

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

Name of organization / entity

Babol University Of Medical Sciences

Full name of responsible person

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Position

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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