Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of intubating conditions and hemodynamic changes using propofol-succinyl choline with remifentanil-propofol for tracheal intubation in patients under General Anesthesia for upper Extremity surgeries

Protocol summary

Summary

The goal of this study is to compare the intubation condition when remifentanil or succinylcholine was used. In this randomized double blind clinical trial, 60 ASA Class I/II, and Mallampati grade of 1 or 2, with 18-70 years old patients and written informed consent, who were candidate for elective upper limb surgery will divided into two groups of 30 each. Patients with ASA class 3 or higher, Mallampati degree 3 or higher and obesity will be excluded. Basal heart rate, blood pressure and Sao2 will be controlled and noted. In group one remifentanyl 2 µg/kg, and propofol 2.5 mg/kg IV will be administered and group two fentanil 50 µg, propofol 2.5 mg/kg, then sucsynilcoline 1 mg/kg IV will be received. After 60 seconds preoxigenation all patients will be intubated. Heart rate and blood pressure will be assessed and recorded. Intubating conditions will be assessed according to the scoring system, including jaw relaxation, vocal cords position, and reaction to tube insertion or cuff inflation. The drugs will be prepared in covered syringes and will be injected blindly with an anesthesiologist who has performed the intubation. Another person who is blinded to the drug injection will control patients during intubation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081310765N10**
Registration date: **2016-12-21, 1395/10/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-12-21, 1395/10/01

Registrant information

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intubating conditions and hemodynamic changes using propofol-succinyl choline with remifentanil-propofol for tracheal intubation in patients under General Anesthesia for upper Extremity surgeries

Public title

Hemodynamic changes during tracheal intubation

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Patients candidates to upper limb surgeries under general anesthesia; patients with ASA class I and II; patients with Mallampaty grade 1 or 2; requested to contribute on study Exclusion criteria: patients with ASA class III or higher; cardiovascular or respiratory patients; brain vascular diseases; intramuscular diseases; patients with Mallampaty grade 3 or higher; obese patients; patients with romanticismal disease; laryngeal or vocal cords disease; preoperative horsness
Age
From **18 days** old to **7 days** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice chancellor for research, Tabriz University of Medical Sciences
Street address
Golgasht Ave, Tabriz University of Medical Scienses,
City
Tabriz
Postal code
Approval date
1995-05-04, 1374/02/14
Ethics committee reference number
IR.TBZMED.REC.1395.426

Health conditions studied

1

Description of health condition studied
Failed or difficult intubation
ICD-10 code
T88.4
ICD-10 code description
Failed or difficult intubation

Primary outcomes

1

Description
Blood Pressure
Timepoint
Imediatly after induction of anesthesia, 3 and 5 minute after induction
Method of measurement
Non invasive BP

2

Description
Heart rate
Timepoint
Imediatly after induction of anesthesia, 3 and 5 minute after induction
Method of measurement
With electrocardiography

Secondary outcomes

1

Description
Heart rate
Timepoint
Imediatly after induction of anesthesia, 3 and 5 minute after induction
Method of measurement
With Elecrocardiogram

Intervention groups

1

Description
Remifentanil will be IV injected through 5-10 seconds, then propofol 2.5 mg/kg administered through 30 seconds. After 60 seconds mask ventilation with oxygen 100% they will be intubated with suitable number of Macintosh laryngoscope (no 3) and tracheal tube laryngoscopy and endotracheal intubation was performed by another anesthesiologist. The cuff was inflated with pressure of 20-25 cmH2O.
Category
Treatment - Drugs

2

Description

Fentanil 50 µg will be IV injected then propofol 2.5 mg/kg administered through 30 seconds. Then sucsynilcoline 1 mg/kg IV will be administered after 60 seconds mask ventilation with oxygen 100% they will be intubated.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada Hospital
Full name of responsible person
Sousan Rasooli
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Reserch center, Tabriz University of Medical Sciences
Full name of responsible person
Elahe Madarek
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Recerch Center, Tabriz University of Medical Sciences, Golgasht Ave
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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
Reserch center, Tabriz 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
Reaserch center, Tabriz University of Medical Scienses
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Person responsible for updating data

Contact

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