

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 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 be 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 succinylcholine 1 mg/kg IV will be received. After 60 seconds preoxygenation 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

Name

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Name of organization / entity

Alzahra hospital/Tabriz University of Medical Sciences

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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 Electrocardiogram

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

Fentanyl 50 µg will be IV injected then propofol 2.5 mg/kg administered through 30 seconds. Then succinylcholine 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**

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Reserch center, Tabriz University of Medical Sciences

Full name of responsible person

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Recerch Center, Tabriz University of Medical Sciences,
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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**

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Web page address**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