

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparison study of the effect of warming and without warming endotracheal tube in facility and complication rates in Blind nasotracheal intubation in maxillofacial surgeries

Protocol summary

Summary

The aim of this study was to compare outcomes of blind Nasotracheal intubation methods with and without warming of endotracheal tube. blind nasotracheal intubation clinically is A method of intubation without Observation of glottis that is used when the orotracheal intubation is difficult or impossible. Blind nasotracheal intubation is recommended in difficult airway algorithm. Of Course the success rate of this method is less and its complications increase. This method is the most common intubating method in difficult intubation conditions that Anesthesiologists are used. Approachs that has been done to minimize nasotracheal Complications Includes the use of lubricants, vasoconstrictor, lower size endotracheal tube and telescoping tube into endotracheal catheters and warming Nasotracheal tube. According to previous studies, the warming endotracheal tube is a good practice because it increases the flexibility of the tube when passes through the high curvature of nasopharynx, and the The result will be less trauma that is important in patients with pathologies that are prone to injury and epistaxis. Therefore, regard to the favorable results of warming the endotracheal tube in Nasotracheal intubation, this study want to answer this question that does warming tracheal tube in Blind nasotracheal intubation for apneic and anesthetized patients increase the success rate of this method? 60 patients for this study were considered. In each group of 30 patients with the use of the Website www.randomizer.org will be divided into two Randomized groups. In both groups Was used a similar Blind nasotracheal intubation method , With this difference that in one group Intubation tube is warm and the other group is not warm. main Exclusion criteria included: 1 - limited mouth opening less than 35 mm 2 - Mallampati III and above 3 - thyromental distance of less than 65 mm 4 - sternomental distance of less than 12.5 cm Main Inclusion criteria were: 1- ASA

physical class I and class II 2 - elective maxillofacial surgeries need to nasal intubation Spss version 16 will be used for analysis of the data . Descriptive statistics (frequency, percentage, mean and standard deviation) will be used to describe the data. T-test will be used for comparison the intubation time and success rate, HR, MBP and SaO2. Chi-square will be used To compare the number of attempts, epistaxis, sore throat and laryngospasm. T-test for age and weight and Chi-square will be used for ASA, type of surgery, Associated Disease and sex. Repeated measured T-test method is used FOR Changes will be measured repeatedly during the procedure, such as HR, MBP and SaO2.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306274731N11**

Registration date: **2013-07-11, 1392/04/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-07-11, 1392/04/20

Registrant information

Name

Hamze Hosseinzade

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1334 7055

Email address

hosseinz@tbzmed.ac.ir

Recruitment status**Recruitment complete****Funding source**

Tabriz University of Medical Sciences

Expected recruitment start date

2013-03-30, 1392/01/10

Expected recruitment end date

2014-01-22, 1392/11/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison study of the effect of warming and without warming endotracheal tube in facility and complication rates in Blind nasotracheal intubation in maxillofacial surgeries

Public title

The effect of endotracheal tube warming on blind nasotracheal intubation

Purpose

Treatment

Inclusion/Exclusion criteria

Exclusion criteria: 1 - limited mouth opening less than 35 mm 2 - Mallampati III and above 3 - thyromental distance of less than 65 mm 4 - limitation of neck movement 5 - sternomental distance of less than 12.5 cm 6 - Patients with a history of recurrent epistaxis 7 - patients with coagulation disorders. 8 - absence of fracture of the skull base Inclusion criteria: 1 - entering the study of patient satisfaction 2 - ASA physical class I and class II 3 - The age of patients ranged from 15 to 65 years 4 - elective maxillofacial surgeries need to nasal intubation

AgeFrom **15 years** old to **65 years** old**Gender**

Both

Phase

N/A

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**

Research Vice -chancellor, Faculty of Dentistry, Tabriz University of Medical Sciences.

Street address

Golgasht, Faculty of Dentistry

City

Tabriz

Postal code**Approval date**

2013-05-07, 1392/02/17

Ethics committee reference number

9222

Health conditions studied**1****Description of health condition studied**

Difficult Airway Management in Maxillofacial Surgery

ICD-10 code

w75-w84

ICD-10 code description

Other accidental threats to breathing (W75-W84)

Primary outcomes**1****Description**

Intubation time

Timepoint

During intubating

Method of measurement

Chronometer

2**Description**

Number of attempts to intubation

Timepoint

During intubation

Method of measurement

Clinical observation

3**Description**

Heart rate

Timepoint

One minute before general anesthesia, three minutes after general anesthesia, and a minute after nasal intubation

Method of measurement

continuous ECG monitoring

4

Description

Mean arterial pressure

Timepoint

One minute before general anesthesia, three minutes after general anesthesia, and a minute after nasal intubation

Method of measurement

monitoring

5

Description

Arterial oxygen saturation

Timepoint

One minute before general anesthesia, three minutes after general anesthesia, and a minute after nasal intubation

Method of measurement

Pulse oximetry

6

Description

Tube position during intubation

Timepoint

During intubation

Method of measurement

Clinical observation

Secondary outcomes

1

Description

Laryngospasm

Timepoint

until 24 hours after extubation

Method of measurement

Clinical observation

2

Description

Intensity of epistaxis

Timepoint

until 24 hours after extubation

Method of measurement

Clinical observation

3

Description

Hoarseness

Timepoint

until 24 hours after extubation

Method of measurement

Clinical observation

4

Description

Sore throat

Timepoint

until 24 hours after extubation

Method of measurement

Ask the patient

Intervention groups

1

Description

Control intervention: doing blind nasotracheal intubation without warming the tracheal tube

Category

Treatment - Devices

2

Description

Case Study: Blind nasotracheal intubation performed by using the softened tube by warm water is 50 ° C for 5 min.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Imam Reza Hospital

Full name of responsible person

doctor Hamzeh Hosseinzadeh

Street address

Imam Reza Hospital, Azadi Street three way
Golgashhtabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research vice-chancellor of Tabriz University of
Medical Sciences

Full name of responsible person

Seyed Kazem Shakouri

Street address

Golgashhtabriz University of Medical Sciences
Medical School Department of Physical Medicine and
Rehabilitation

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Research vice-chancellor of 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**

Tabriz University of Medical Sciences

Full name of responsible person

Hamzeh Hosseinzadeh

Position

Associate Professor

Other areas of specialty/work**Street address**

Golgasht ,Imam Reza Hospital

City

Tabriz

Postal code**Phone**

+98 41 1334 7055

Fax**Email**

hosseinz@tbzmed.ac.ir; g.hosein@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Hamzeh Hosseinzadeh

Position

Associate Professor

Other areas of specialty/work**Street address**

Golgasht Imam Reza Hospital

City

Tabriz

Postal code**Phone**

+98 41 1334 7055

Fax**Email**

hosseinz@tbzmed.ac.ir; g.hosein@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Hossein Gholizadeh

Position

MD

Other areas of specialty/work**Street address**

Golgasht Imam Reza Hospital

City

Tabriz

Postal code**Phone**

+98 41 1444 3914

Fax**Email**

hosseinz@tbzmed.ac.ir; g.hosein@yahoo.com

Web page address**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