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 surgries

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-squre will be used To compare the number of attempts, epistaxis, sore throat and laryngospasm. T-test for age and weight and Chi-squre 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

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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 surgries

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
Age
From **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 Golgasht.Tabriz
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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
Golgasht Tabriz 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
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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