Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of facility and complications of nasal intubation with and without Gum Elastic Bougie guided by Glidoscope in patients undergoing Maxillofacial Surgeries in Sina Hospital

Protocol summary

Summary

Objectives: The aim of this study is assessing the effects of gum elastic bougie on Ease and complications of Nasotracheal intubation guided by Glidoscope.In addition, Trauma to soft tissue and Intubation time will be assessed. Design: Patients between 15 to 65-year old, who agrees inclusion criteria, will be studied.160 patients, ASA class I and II who undergoes maxillofacial surgeries with general anesthesia and nasotracheal intubation,are equally and randomly put in control and case groups. Setting and conduct: Nasotracheal intubation is done as standard method in control patients and with gum elastic bougie in case group. Participants and major eligibility criteria: All patients who undergoes maxillofacial surgery and needs nasotracheal intubation are included in this study. Patients with difficult or compromised airway and coagulopathy will be excluded from this study. Intervention: Intervention of this study is performing nasotracheal with Bougie guide. Main outcome measures variables: Attempts to successful intubation, Trauma to soft tissue, Bleeding and rate of complications will be recorded and compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201309247604N1**
Registration date: **2014-08-15, 1393/05/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-08-15, 1393/05/24

Registrant information

Name

Ailar Ahangari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4441 8799

Email address

melikaahangari@gmail.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2014-10-22, 1393/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of facility and complications of nasal intubation with and without Gum Elastic Bougie guided by Glidoscope in patients undergoing Maxillofacial Surgeries in Sina Hospital

Public title

Nasal Intubation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients undergo maxillofacial

surgeries who need nasotracheal intubation; age between 15 to 65; ASA class I and II. Exclusion criteria: patient younger than 15-year-old; patients with difficult or compromised airway; patients who have restrictions in mouth opening; coagulopathy; patients who don't have neurosurgery permission for nasal intubation; cases who need size 6 of tracheal tube or less; emergency or non-elective surgery.

Age
From **15 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **160**

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 Tehran university of Medical sciences

Street address
Central building of university, Ghods St., Keshavarz boulvard, Tehran.

City
Tehran

Postal code

Approval date
2014-06-10, 1393/03/20

Ethics committee reference number
92-03-30-23881-117261

Health conditions studied

1

Description of health condition studied
Nasotracheal Intubation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Need to use Magill Forceps

Timepoint
During intubation, After intervention

Method of measurement
using or not using Magill During intubation

2

Description
Effects of using Bougie in reducing numbers of attempts to nasal intubation

Timepoint
After Intubation

Method of measurement
Count the number of trials

Secondary outcomes

1

Description
Bleeding

Timepoint
During intubation, After intervention

Method of measurement
Observation and confirmation of anesthesiologist

2

Description
Need to use Direct Laryngoscopy via Machintosh Laryngoscope

Timepoint
During intubation, After intervention

Method of measurement
Use of Machintosh Laryngoscope for intubation

3

Description
Trauma to soft tissue of mouth and soft palate

Timepoint
During intubation, After intervention

Method of measurement
Observation and confirmation of anesthesiologist

4

Description
Total time of intubation

Timepoint
From begining to the end of intubation process

Method of measurement
chornometer

Intervention groups

1

Description
In case group, Nasal intubation will be guided by Glydoscope with bougie.
Category
Prevention

2

Description
In control group, Nasal intubation will be guided by Glydoscope without bougie.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Pejman Pourfakhr
Street address
Sina hospital, Hasan abad sq., Emam Khomeini st., Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Dr. Pejman Pourfakhr
Street address
Vice chancellor, Central building of Tehran univercity of medical science,Ghods st., Keshavarz Ave.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Ailar Ahangari
Position
Student of Medicine
Other areas of specialty/work
Street address
Sina hospital, Hasan abad sq., Emam Khomeini st., Tehran
City
Tehran
Postal code
Phone
+98 21 6634 8500
Fax
Email
pejmanpourfakhr@yahoo.com; melikaahangari@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Sina Hospital
Full name of responsible person
Pejman Pourfakhr
Position
Assistant professor
Other areas of specialty/work
Street address
Sina hospital, Hasan abad sq., Emam Khomeini st., Tehran
City
Tehran
Postal code
Phone
+98 21 6634 8500
Fax
Email
pejmanpourfakhr@yahoo.com; melikaahangari@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ailar Ahangari

Position
Student of Medicine
Other areas of specialty/work
Street address
Sina hospital, Hasan abad sq., Emam Khomeini st., Tehran
City
Tehran
Postal code
Phone
+98 21 6634 8500
Fax
Email
pejmanpourfakhr@yahoo.com; melikaahangari@gmail.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