

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 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 boulevard, 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 beginning 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