Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of success and side effects between standard nasotracheal intubation and bougie guide among mandible surgery patients reffered to poursina hospital in 2013

Protocol summary

Summary

Nasotracheal intubation is often required for dental and oral surgery. In conventional nasal intubation, direct laryngoscopy using the Macintosh laryngoscope and Magill forceps or the fiberoptic bronchoscope is applied. However, both of these methods are somewhat difficult to master by personnel who do not often perform nasotracheal intubation. The objective of this study was to assess effectiveness of gum elastic bougie (GEB) in nasotracheal intubation. The bougie is inexpensive, has few complications and is easy to use. We recommend that GEB should be applied from the first attempt for nasal intubation in patients with mandibular truma.60 adult, ASA physical status 1 and 2 patients requiring nasotracheal intubation for mandibular surgery devided in two group randomized. The first group will intubated with standard nasotracheal approach and nasal intubation in the second group do with bougie guide. At first bougie passed the nose and enters to trachea with Macintosh laryngoscope and Magill forceps guide then tracheal tube is rdmy over the bougie into the trachea and bougie is removed. All of the preoperative preparation And induction process is aqual in tow groups and some items such as success rate and complications should be registered inclouding oxygen desaturation, heart rate changes, time of intubation, attemps of intubation, nose truma, need to tube exchange and cuff rupture.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306086280N3**
Registration date: **2013-09-07, 1392/06/16**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2013-09-07, 1392/06/16

Registrant information

Name

Mohammad Haghighi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3211 1319

Email address

mohaghighi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2013-10-08, 1392/07/16

Expected recruitment end date

2014-09-07, 1393/06/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of success and side effects between standard nasotracheal intubation and bougie guide among mandible surgery patients reffered to poursina hospital in 2013

Public title

Comparison of success and morbidity in both standard and ways in nasotracheal intubation bougie in patients with mandibular surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age 20 to 60 years old; ASA I,II; surgical intubation for nasotracheal intubation; GCS:15 and neurosurgery visit; normal PT,PTT and PLT. Exclusion criteria: sinusitis; nasal deformity or trauma and patient dissatisfaction.

Age

From **20 years** old to **60 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

Guilan University of Medical Sciences

Street address

Namjoo street

City

Rasht

Postal code

4193833697

Approval date

2013-06-17, 1392/03/27

Ethics committee reference number

1920101205

Health conditions studied

1

Description of health condition studied

Nasotracheal intubation

ICD-10 code

N42.3

ICD-10 code description

Dysplasia of prostate Low grade dysplasia

Primary outcomes

1

Description

Oxygen desaturation rate

Timepoint

During intubation

Method of measurement

Pulse Oximeter/%

2

Description

Heart rate variations

Timepoint

During intubation

Method of measurement

Monitoring / number

3

Description

Intubation duration

Timepoint

From starting endotracheal intubation to correctly position

Method of measurement

Second/ Capnograph

4

Description

Attempts to intubation times

Timepoint

During intubation

Method of measurement

Times

5

Description

Nose trauma

Timepoint

During extubation

Method of measurement

Visual/ Blood in throat or on the cuff

6

Description

Tracheal tube change

Timepoint

During intubation

Method of measurement

Tube exchange to a smaller size

7

Description
Cuff ruptured
Timepoint
During intubation
Method of measurement
Visual/No filled cuff after intubation

Secondary outcomes

empty

Intervention groups

1

Description
Nasotracheal intubation group or a control group that is standard procedure and does not interfere
Category
Prevention

2

Description
Intervention group nasotracheal intubation is performed with bogies
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Poursina Hospital
Full name of responsible person
Mohamad Haghighi
Street address
Parastar Street
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Abdolrasool Sobhani
Street address
Shahid Beheshti Highway
City
Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Guilan 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
Guilan University of Medical Sciences
Full name of responsible person
Mohamad Haghighi
Position
Anesthesiologist/Associated Professor
Other areas of specialty/work
Street address
Poursina Hospital
City
Rasht
Postal code
4193713194
Phone
+98 13 1322 3970
Fax
+98 13 1323 9842
Email
ARC@gums.ac.ir; vbuh.research@gmail.com; mohaghighi@gums.ac.ir
Web page address
www.gums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Mohamad Haghighi
Position
Associated Professor
Other areas of specialty/work
Street address
Poursina Hospital
City
Rasht
Postal code
4193713194
Phone
+98 13 1322 3970
Fax
+98 13 1323 9842

Email
ARC@gums.ac.ir; mohaghighi@gums.ac.ir; vbuh.research@gmail.com
Web page address
www.gums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Mohamad Haghighi
Position
Anesthesiologist/Associated Professor
Other areas of specialty/work
Street address
Poursina Hospital
City
Rasht
Postal code
4193713194
Phone
+98 13 1322 3970
Fax
+98 13 1323 9842
Email
ARC@gums.ac.ir; mohaghighi@gums.ac.ir; vbuh.reseasarch@gmail.com
Web page address
www.gums.ac.ir

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