

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The comparison of success and side effects between standard nasotracheal intubation and bougie guide among mandible surgery patients referred 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 trauma. 60 adult, ASA physical status 1 and 2 patients requiring nasotracheal intubation for mandibular surgery divided into two groups randomized. The first group will be intubated with standard nasotracheal approach and nasal intubation in the second group done with bougie guide. At first bougie passed the nose and enters to trachea with Macintosh laryngoscope and Magill forceps guide then tracheal tube is slid over the bougie into the trachea and bougie is removed. All of the preoperative preparation and induction process is equal in two groups and some items such as success rate and complications should be registered including oxygen desaturation, heart rate changes, time of intubation, attempts of intubation, nose trauma, 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

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Name of organization / entity

Guilan University of Medical Sciences

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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 referred 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

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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