Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Comparison the prevalence of sore throat due to endotracheal intubation with videolaryngoscope (Glidoscope) and conventional laryngoscope Macintosh and placement the LMA in elective surgeries

Protocol summary

Study aim

Comparison the prevalence of sore throat due to endotracheal intubation with videolaryngoscope (Glidoscope) and conventional laryngoscope Macintosh and placement the LMA in elective surgeries

Design

Study design: clinical trial. Number of groups: 3 Total sample size: 90 patients. Sample size in each group: 30 people Randomization: random packs that opened precisely before the start of surgery. Blinding: a person outside the study and unaware of the study process (double-blind study).

Settings and conduct

Location: Shahid Rajaee & Velayat hospitals in Qazvin city, Iran. Study Methods: patients were randomly assigned to one of the study groups. Patient's monitoring was performed using ECG (electrocardiogram), pulse oximetry and barometric measurements. All patients received 2 mg/kg body weight fentanyl and 0.2 mg/kg body weight midazolam as a precursor and then propofol was given at a dose of 2.5-2 mg / kg body weight and atracurium at a dose of 0.5 mg/kg of body weight, anesthetic induction was prescribed. Patients were treated with 100% oxygenation mask for 3 minutes; then the G group was subjected to intubation with blade number 3; the M group was also implanted with blade 3 of the Macintosh laryngoscope and the L group was placed under the LMA placement. After fixing the tube or LMA, an oxygen concentration of 100% plus TIVA (propofol infusion) was administered to each of the three groups of patients for anesthesia (N2O not prescribed for any patient), and repeated fentanyl injection was used for maintaining analgesia. The number of patients with sore throat in the 8-6 hours and 24 hours after surgery was recorded in all three groups using questionnaire. The length of the laryngoscopy (that is measured by the number of seconds from the time the laryngoscope enters the mouth, until the tracheal tube passes) was recorded via vocal cords. For each patient, the duration of the laryngoscopy until the insertion of the tracheal tube and the number of attempts to intubate by seconds were measured and recorded. The length of the LMA placement was measured and recorded from the time it was inserted into the mouth until it was placed in Pharenx. Also in all patients, hemodynamic parameters including heart rate, systolic blood pressure, diastolic blood pressure and mean blood pressure were recorded one minute before induction of anesthesia and also in the 3rd and 5th minutes after intubation or LMA insertion.

Participants/Inclusion and exclusion criteria

Inclusion criteria: presence of ASA (American Society of Anesthesiology Status) Class I or II; age between 20 to 40 years old; patients undergoing any elective surgery (except for head and neck surgery) and requiring general anesthesia. Non-admission criteria: aspiration and vomiting during induction of anesthesia and laryngoscopy; the presence of any lesion or active disease in the head and neck area and the airway such as pharyngitis or laryngeal mass during pre-anesthetic visit; head and neck surgery; cardiovascular, respiratory, neovascular and cardiovascular and rheumatic disorders; high risk of aspirating (diabetic patients, incomplete NPO time, addicted patients); history of difficult Intubation Length of surgery for more than 2 hours; possible problems for intubation in the clinical examination; length of intubation or LMA insertion time greater than 20 seconds.

Intervention groups

1) Direct laryngoscopy group via Macintosh blade (M) 2)]ndirect laryngoscopy group via gladioscope (G) 3) Group (L) by inserting LMA

Main outcome variables

Sore throat at intervals of 8-6 hours and 24 hours after intubation

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180207038661N1**
Registration date: **2018-02-18, 1396/11/29**
Registration timing: **retrospective**

Last update: **2018-02-18, 1396/11/29**
Update count: **0**
Registration date
2018-02-18, 1396/11/29

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-01-21, 1396/11/01
Expected recruitment end date
2018-03-11, 1396/12/20
Actual recruitment start date
2017-06-23, 1396/04/02
Actual recruitment end date
2017-12-15, 1396/09/24
Trial completion date
empty

Scientific title
Comparison the prevalence of sore throat due to endotracheal intubation with videolaryngoscope (Glidoscope) and conventional laryngoscope Macintosh and placement the LMA in elective surgeries

Public title
Comparison sore throats caused by the three main techniques of intracranial intubation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Presence of ASA (American Society of Anesthesiology Status) Class I or II Age between 20 to 40 years old Patients undergoing any elective surgery (except for head and neck surgery) and requiring general anesthesia.
Exclusion criteria:
Aspiration and vomiting during induction of anesthesia and laryngoscopy The presence of any lesion or active disease in the head and neck area and the airway such as pharyngitis or laryngeal mass during pre-anesthetic visit Head and neck surgery Cardiovascular, respiratory, neovascular and cardiovascular and rheumatic disorders High risk of aspirating (diabetic patients, incomplete NPO time, addicted patients) History of difficult Intubation Length of surgery for more than 2 hours Possible problems for intubation in the clinical examination Length of intubation or LMA insertion time greater than 20 seconds
Age
From **20 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**
Actual sample size reached: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomization and placement of patients in one of the study groups we used random packets. In this way, the researcher randomly opened one of the envelopes before the anesthetic induction and at that moment the technique was chosen for the patient.
Blinding (investigator's opinion)
Double blinded
Blinding description
Packets used for randomization, were prepared by someone else who were not included in the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Biomedical Research of Qazvin University of Medical Sciences
Street address
Qazvin University of Medical Sciences, Bahonar Bulivard, Qazvin, Iran
City
Qazvin
Province
Qazvin
Postal code

34197-59811

Approval date
2016-11-26, 1395/09/06

Ethics committee reference number
IR.QUMS.REC.1395.192

Health conditions studied

1

Description of health condition studied
Patients undergoing elective surgeries (Non-emergent)

ICD-10 code
Z41.9

ICD-10 code description
Procedure for purposes other than remedying health state, unspecified

Primary outcomes

1

Description
Sore-throat

Timepoint
6-8 hours and 24 hours after intubation

Method of measurement
Asking question from patient

Secondary outcomes

1

Description
Systolic Blood Pressure

Timepoint
Before starting, Min 3 after starting, Min5 after starting

Method of measurement
Barometer

2

Description
Diastolic Blood Pressure

Timepoint
Before starting, Min 3 after starting, Min5 after starting

Method of measurement
Barometer

3

Description
Mean Blood Pressure

Timepoint
Before starting, Min 3 after starting, Min5 after starting

Method of measurement
Mathematical Calculation

4

Description
Heart Rate

Timepoint
Before starting, Min 3 after starting, Min5 after starting

Method of measurement
Heart Monitoring

5

Description
Duration of intubation or LMA embedding

Timepoint
Once, During the procedure

Method of measurement
Chronometer

6

Description
The duration between laryngoscopy until the insertion of the tracheal tube

Timepoint
Once, During the procedure

Method of measurement
Chronometer

7

Description
The number of attempts for intubation or LMA placement

Timepoint
Once, During the procedure

Method of measurement
Anesthesiologist

Intervention groups

1

Description
Group 1: Direct laryngoscopy with Macintosh blade

Category
Treatment - Surgery

2

Description
Group 2: Indirect laryngoscopy by glidoscope

Category
Treatment - Surgery

3

Description
Group 3: Laryngeal mask airway (LMA) insertion

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Rajaee Hospital

Full name of responsible person
Mohammad Ali Masoumi far
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Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Mohammad Ali Masoumi far
Position
دستیار بیهوشی
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
I have not yet decided on this.

When the data will become available and for how long
I have not yet decided on this.

To whom data/document is available
I have not yet decided on this.

Under which criteria data/document could be used
I have not yet decided on this.

From where data/document is obtainable
I have not yet decided on this.

What processes are involved for a request to access data/document
I have not yet decided on this.

Comments