Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of success rate of tracheal intubations between two methods; the LMAfastrach and AirQ- ILA in patients undergoing elective surgery during general anesthesia

Protocol summary

Study aim

Success rate of tracheal intubation in LMAfastrach and AirQ-ILA groups

Design

Clinical trial, with parallel groups, single blinded study with block randomization

Settings and conduct

This single blinded study will take place in Firoozgar and Rassol Akram hospitals. Patients will be selected for study groups through Block-Randomized method. After their arrival to the operation room and monitoring application, the patients will go under general anesthesia. After induction, the supraglottic device is inserted, if the ventilation is successful, the time duration of this insertion will be recorded. After that, tracheal intubation via supraglottic device will be done and if ventilation has gone successfully, the duration of intubation will be recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Fasting, Age: 18-60 years, ASA :1,2 , written informed consent, Thyromental distance more than 6 cm, Mallampathy score: 1,2,3 , Opening of mouth more than two finger width. Exclusion criteria : Gasteroesophageal Reflux Disease, Body Mass Index more than 30 kg/M2, Contraindication for administration of anesthetic drug, History of difficult airway, Mallampathy score more than 3, Patient's dissatisfaction

Intervention groups

Determination of success rate of intubation with two type of supraglottic devices : LMAfastrach ,AirQ-ILA

Main outcome variables

Determination of success rate of tracheal intubation will be compared between two group: AirQ-ILA and LMAfastrach in patients candidate for elective surgery under general anesthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151107024909N7**
Registration date: **2018-07-05, 1397/04/14**
Registration timing: **retrospective**

Last update: **2018-07-05, 1397/04/14**
Update count: **0**

Registration date

2018-07-05, 1397/04/14

Registrant information

Name

Faranak Rokhtabnak

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 6267

Email address

rolhtabnak.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

2016-03-20, 1395/01/01

Actual recruitment end date

2016-12-20, 1395/09/30

Trial completion date

empty

Scientific title
Comparison of success rate of tracheal intubations between two methods; the LMAfastrach and AirQ- ILA in patients undergoing elective surgery during general anesthesia

Public title
Success rate of tracheal intubation with LMAfastrach and AirQ-ILA

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
Fasting Age :18-60 years Informed consent Thyromental distance more than 6 Cm Mouth opening more than two finger width Mallampati Score:1,2

Exclusion criteria:
Gastoesophageal Reflux Disease Body Mass Index more than 30 Contraindication for administration of anesthetic drugs History of difficult intubation in previous surgeries Patient Dissatisfaction

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **126**
Actual sample size reached: **126**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be allocated to one study group by using block randomization.One hundred and twenty six patients will be divided in twenty one blocks including six patients and each block ,which will be placed in a sealed envelope, will be chosen randomly for patients.

Blinding (investigator's opinion)
Single blinded

Blinding description
The patient in each group is unaware of the study group she/he is involved in.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Iran University of Medical Sciences

Street address
Firoozgar Hospital, Beh-Afarin Ave., Vali-e-Asr Sq.

City
Tehran

Province
Tehran

Postal code
1593748711

Approval date
2016-02-06, 1394/11/17

Ethics committee reference number
IR.IUMS.REC 1394.9211174014

Health conditions studied

1

Description of health condition studied
Airway managment

ICD-10 code
T88.4

ICD-10 code description
Failed or difficult intubation

Primary outcomes

1

Description
Success rate determination of tracheal intubation in LMAfastrach and AirQ-ILA groups

Timepoint
Duration of implementation of two types of supraglottic devices and tracheal intubation via supraglottic device in LMAfastrach and AirQ-ILA groups

Method of measurement
Stopwatch

Secondary outcomes

1

Description
1-Hoarseness

Timepoint
When the patient is fully awake in recovery room

Method of measurement
By talking to patient

Intervention groups

1

Description
Group 1: LMAfastrach, Laryngeal Mask Company, Jersey, UK, reusable, silicon

Category

Diagnosis

2

Description
Group 2: AirQ-ILA- A new device for airway establishment, re-usable silicon and plastic, Coogas LLC., St. Louis, MO, Size 2-5
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar Hospital
Full name of responsible person
Mahdi Farnaghizad
Street address
Firoozgar hospital, Behafarin Ave., Vali-e-Asr Sq.
City
Tehran
Province
Tehran
Postal code
1593748711
Phone
+98 21 8214 1000
Fax
+98 21 8894 2622
Email
H-Firoozgar@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr.Seyed Kazem Malakoti
Street address
Iran University of Medical Sciences, next to Milad Tower, Hemat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 86701
Fax
+98 21 8862 2532
Email
PR@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Dr.Faranak Rokhtabnak
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Firoozgar hospital, Behafarin Ave., Vali-e-Asr Sq.
City
Tehran
Province
Tehran
Postal code
1593748711
Phone
+98 21 8894 6762
Fax
+98 21 8894 2622
Email
rkhtbnk@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Faranak Rokhtabnak
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Firoozgar Hospital, Behafarin Ave. , Vali-e-Asr Sq.
City
Tehran

Province
Tehran
Postal code
1593748711
Phone
+98 21 8894 6762
Fax
+98 21 8894 2622
Email
rkhtbnk@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mahdi Farnaghizad
Position
Assistant of anesthesia
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Firoozgar hospital, Behafarin Ave., Vali-e-Asr Sq.
City
Tehran
Province
Tehran
Postal code
1593748711
Phone
+98 21 8894 6762
Fax
+98 21 8894 2622
Email
farnaghi@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Thesis of resident- Article
When the data will become available and for how long
Until 6 years after publication
To whom data/document is available
Reviewers and editors of journals; Authorities of university; other reserchers
Under which criteria data/document could be used
Request of reviewer of article
From where data/document is obtainable
Dr. Faranak Rokhtabnak- rkhtbnk@yahoo.com
What processes are involved for a request to access data/document
Submitting a written request- Guarantee to maintain information - Delivery of information to privet page of applicant
Comments