

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 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 : Gastroesophageal 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:

Gastroesophageal 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 management

### 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

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**Fax**

+98 21 8894 2622

**Email**

rkhtbnk@yahoo.com

**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****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

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