

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Comparison of i-Gel and Air-Qsp for airway management in patients under general anesthesia.

#### Protocol summary

##### Summary

The aim of this study is Comparison of i-Gel and Air-Qsp for airway management in patients under general anaesthesia and comparison time airway instrument of insertion and peak airway pressure. This is a single-blind study in 40 patient in both gender with ASA class I and II and our study anaesthetized paralysed patients who candidate for minor elective surgery in Shahid Modares Hospital. The patients will randomly be allocated into 2 groups with Table of random numbers. First group airway will manage with I-gel(n=20) and second with Air-Q(n=20). The patients will be blind in this study. Inclusion criteria patient underwent elective operation who required general anaesthesia with neuromuscular blocker under ventilator support, ASA Class III, Age18\_70, Consented, Inguinal hernia Surgery, varicocele surgery. Exclusion criteria Cardiac disease with ASA III\_IV, Age older than 70 or younger than18, Requires urgent operation, Prolong Operation( lasted more than 2 hours ). Prior to anaesthetic induction a 18 intravenous catheter will be inserted to give fluid and medication. After induction with Propofol 2.5mg/kg and atracurium, 0.5mg/kg the supraglottic device will be inserted and anaesthesia technician will measure the time of insertion. After that, manual ventilation will consider for leak pressure test and will register high pressure with the air leak and patient ventilate under control ventilation with Tidal volume=5-6 cc/kilogram, Rate=12, Pressure Maximum=25 cmH2O.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016081512203N8**

Registration date: **2017-10-07, 1396/07/15**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-10-07, 1396/07/15

##### Registrant information

###### Name

Niloufar Massoudi

###### Name of organization / entity

Shahid Beheshti University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 26 3250 6961

###### Email address

nmasoudi@qums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Shahid Beheshti University of medical science

##### Expected recruitment start date

2017-05-26, 1396/03/05

##### Expected recruitment end date

2017-10-23, 1396/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of i-Gel and Air-Qsp for airway management in patients under general anesthesia.

##### Public title

Comparison of i-Gel and Air-Qsp for airway management in patients under general anesthesia.

##### Purpose

Supportive

## **Inclusion/Exclusion criteria**

Inclusion criteria: Patient underwent elective operation who required general anaesthesia with neuromuscular blocker under ventilator support, ASA Class I -II, Age 18\_70, Consented, Inguinal hernia Surgery, varicocele surgery. Exclusion criteria: Cardiac disease with ASA III\_IV, Age older than 70 or younger than 18, Requires urgent operation, Prolong Operation (lasted more than 2 hours)

## **Age**

From **18 years** old to **70 years** old

## **Gender**

Both

## **Phase**

2

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **0**

## **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**

Ethics committee of Shahid Bheshti University of Medical Sciences.

##### **Street address**

Shahid Beheshti Medical university, Arabi street, Velenjak.

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2017-05-24, 1396/03/03

#### **Ethics committee reference number**

IR.SBMU.RETECH.REC.1396.129

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Inguinal hernia surgery

#### **ICD-10 code**

K40

#### **ICD-10 code description**

Bilateral inguinal hernia, with obstruction, without gangrene

### 2

#### **Description of health condition studied**

Scrotal varices surgery

#### **ICD-10 code**

I86.1

#### **ICD-10 code description**

dilated tortuous veins of the spermatic cord

## **Primary outcomes**

### 1

#### **Description**

maximum inspiration pressure that exist leak

#### **Timepoint**

first second and 30 minute after start of surgery

#### **Method of measurement**

cmHg

## **Secondary outcomes**

### 1

#### **Description**

End expiratory carbon dioxide pressure

#### **Timepoint**

first second and 30 minute after start of surgery

#### **Method of measurement**

capnography

## **Intervention groups**

### 1

#### **Description**

Intervention: Use of Air-Q

#### **Category**

Treatment - Other

### 2

#### **Description**

Control Group: Use of I-Gel

#### **Category**

Diagnosis

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shahid Modares Hospital

##### **Full name of responsible person**

Nilofar Massoudi

**Street address**

Shahid Modares Hospital, Sadat Abad.

**City**

Tehran

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Behesht University of Medical Science

**Full name of responsible person**

Nilofar Massoudi

**Position**

Anesthesiologist

**Other areas of specialty/work****Street address**Shahid Behesht University of Medical Science,  
Modares Hospital. Sadat Abad.**City**

Tehran

**Postal code****Phone**

+98 21 2207 4088

**Fax****Email**massodi@sbmu.ac.ir, fsafari@sbmu.ac.ir,  
alidabbagh@sbmu.ac.ir.**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Vice chancellor for the research Shahid Beheshti  
University of Medical Science.**Full name of responsible person**

Nilofar Massoudi

**Street address**Shahid Modares Hospital, Shahid Beheshti Medical  
Science University, Sadat Abad, Tehran, Iran**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**Vice chancellor for the research Shahid Beheshti  
University of Medical Science.**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**

Shahid Beheshti Medical University

**Full name of responsible person**

Nilofar Massoudi

**Position**

Anesthesiologist

**Other areas of specialty/work****Street address**Shahid Beheshti Medical University, Modares  
Hospital, Sadat Abad.**City**

Tehran

**Postal code****Phone**

+98 21 2207 4088

**Fax****Email**massodi@sbmu.ac.ir, fsafari@sbmu.ac.ir,  
alidabbagh@sbmu.ac.ir.**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Behesht University of Medical Science

**Full name of responsible person**

Nilofar Massoudi

**Position**

Anesthesiologist

**Other areas of specialty/work****Street address**Shahid Behesht University of Medical Science,  
Modares Hospital, Sadat Abad.**City**

Tehran

**Postal code****Phone**

+98 21 2207 4088

**Fax****Email**massodi@sbmu.ac.ir, fsafari@sbmu.ac.ir,  
alidabbagh@sbmu.ac.ir.**Web page address****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*