

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, 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). 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 addressShahid 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 sourceVice 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

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Modares Hospital, Sadat Abad.**City**

Tehran

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+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