

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of Pofoll, Isoflurane and Nitric oxide on endotracheal tube cuff pressure in patients undergoing elective surgery with general anesthesia

#### Protocol summary

##### Summary

The aim of this study is to evaluate changes of tracheal tube cuff pressure in elective surgeries and prevention from complications of high or Low cuff pressure. All of 18 to 65 years old patients undergoing elective surgery that do not have head, neck and thorax surgery and their surgery last more than 90min under general anesthesia with tracheal intubation will be evaluated. 134 patients will be randomly assigned to 4 groups Pofoll, Propofol, Isoflurane and Nitric oxide, and the cuff pressure will be checked after intubation and every 30 minutes

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014090412642N4**  
Registration date: **2014-10-04, 1393/07/12**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2014-10-04, 1393/07/12

##### Registrant information

###### Name

Majid Golestani Eraghi

###### Name of organization / entity

Shahid Beheshti University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 3336 0547

###### Email address

dr.golestani@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research of Arak University of Medical Sciences

##### Expected recruitment start date

2014-10-23, 1393/08/01

##### Expected recruitment end date

2015-03-21, 1394/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of Pofoll, Isoflurane and Nitric oxide on endotracheal tube cuff pressure in patients undergoing elective surgery with general anesthesia

##### Public title

The effect of anesthetic agents on tracheal tube cuff pressure

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

inclusion criteria: Patients undergoing elective surgery; ASA class I and II exclusion criteria: Patients outside the age range 15 to 65 years; patients with a high ASA class II; patients with systemic disease heart- lung, renal endocrine or metabolic; morbid obesity (BMI>40); Surgical practice time for less than 1.5 hour; positions other than supine; head and neck and thoracic surgery; neck rotation during surgery more than 10 degrees; Endotracheal tube cuff pressure increases to more than 40 cmH2o during anesthesia; difficult intubation

##### Age

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **136****Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Arak University of Medical Sciences

**Street address**

Ethical committee of Research of Arak University of Medical Sciences, Sardasht Square, Arak

**City**

Arak

**Postal code****Approval date**

2014-06-16, 1393/03/26

**Ethics committee reference number**

93-164-1

**Health conditions studied****1****Description of health condition studied**

tracheal intubation

**ICD-10 code**

T88.7

**ICD-10 code description**

Unspecified adverse effect of drug or medicament

**Primary outcomes****1****Description**

tracheal cuff pressure

**Timepoint**

Before the experiment and then every 30 minutes

**Method of measurement**

In millimeters of mercury using a cuff pressure manometer

**Secondary outcomes****1****Description**

blood pressure

**Timepoint**

end of study

**Method of measurement**

Manometer to measure the pressure

**2****Description**

heart rate

**Timepoint**

end of study

**Method of measurement**

with pulse oxymetry

**Intervention groups****1****Description**

(group A) use of intravenous hypnotic anesthetic (propofol) with dosage of 150ug/kg/min have received in during general anesthesia

**Category**

Early detection

**2****Description**

(group B) use of volatile anesthetic (isofluranl) 1% in during general anesthesia

**Category**

Early detection

**3****Description**

(group C) use of Patients in the intravenous hypnotic anesthetic (propofol) with dosage of 150ug/kg/min with N2o ratio 50-50 in general anesthesia

**Category**

Early detection

**4****Description**

(group D) use of volatile anesthtic(isofluran) 1% with N2O ratio 50-50in general anesthesia

**Category**

Early detection

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Valiasr Hospital

**Full name of responsible person**

Majid Golestai Eraghi

**Street address**

Valiasr square

**City**

Arak

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Majid Golestani Eraghi

**Position**

Anesthesiologist

**Other areas of specialty/work**

**Street address**

Valiasr hospital, valiasr square, Arak

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**Phone**

+98 86 3222 2003

**Fax**

**Email**

dr.golestani@arakmu.ac.ir

**Web page address**

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice Chancellor of Research of Arak University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Rafiee

**Street address**

Vice Chancellor of Research of Arak University of Medical Sciences, Sardasht Square, Arak,

**City**

Arak

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor of Research of Arak University of Medical Sciences

**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**

## Person responsible for scientific inquiries

**Contact**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Arak University Of Medical Science

**Full name of responsible person**

Majid Golestani Eraghi

**Position**

Anesthesiologist

**Other areas of specialty/work**

**Street address**

Valiasr Hospital, Valiasr Square

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dr.golestani@arakmu.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*