Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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

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
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Majid Golestani Eraghi
Position
Anesthesiologist
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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