Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of the Effectiveness of Pressure and Volume controlled Ventilation on the Intracuff Pressure and Air Leakage around the Cuff of the Endotracheal Tube in anesthetized and Mechanically ventilated Patients

Protocol summary

Study aim

Determination and Comparison of the Effect of Pressure controlled Ventilation Mode and Volume controlled Ventilation Mode on Cuff Pressure and Air Leakage around the Cuff of the Endotracheal Tube in Patients under general Anesthesia and Mechanical Ventilation.

Design

Clinical Trial with Control Group, with parallel Groups, Triple blind, randomized

Settings and conduct

In this Study, 50 Patients with open-ended Surgery and Inguinal Hernia in the Operating Room of Imam Hossein Hospital of Shahroud were randomly divided into Two Groups: P and V. The P Group is placed on the PCV Mode and the V Group is placed on a VCV Mode. Initially, the Cuff Pressure will be adjusted to 25 Cmh2o for Both Groups. After the Intervention, the Cuff Pressure and the Amount of CO2 in the Supra-Glottic Space in Both Groups were measured and recorded after 10, 20 and 30 Minutes. Patients, the Person who measures the Variables and the Data Analyzer, respectively, with Anesthesia, Covering the Ventilator Mode and Coding the Two Groups of P and V into A and B, are blinded.

Participants/Inclusion and exclusion criteria

Patients aged 18-40 Years old and Ready for open-ended Surgery and Inguinal Hernia in supine Position, ASA1&2 and BMI=18-24.

Intervention groups

In Group P (Intervention), Patients are placed on the PCV Mode (the Intervention in this Study) and the Airway Pressure is adjusted to reach a Volume of 7ml / kg and in Group V (Control), Patients will be placed on the VCV Mode (Routine Ventilation Mode) and a Tidal Volume of 7 ml / kg will be adjusted. Cuff Pressure and the Amount of CO2 (as an Indicator of Air Leakage) in the Supra glottic Space (with Capnograph) is measured and recorded in both Groups after 10, 20 and 30 Minutes, and compared together will be.

Main outcome variables

Changes in Cuff Pressure of the Endotracheal Tube; Changes in the Amount of Air Leakage around the Cuff

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181018041376N1**
Registration date: **2019-02-23, 1397/12/04**
Registration timing: **prospective**

Last update: **2019-02-23, 1397/12/04**
Update count: **0**

Registration date

2019-02-23, 1397/12/04

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date
2019-06-21, 1398/03/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Pressure and Volume controlled Ventilation on the Intracuff Pressure and Air Leakage around the Cuff of the Endotracheal Tube in anesthetized and Mechanically ventilated Patients

Public title
The Effectiveness of Pressure and Volumetric Ventilation Modes on the Cuff Pressure of Endotracheal Tube and Air Leakage
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18 to 40 Years old and Ready for open-cut Surgery and Inguinal Hernia in supine Position (Patients in Class 1 & 2 Anesthetic Classification for Surgery) ASA 1&2 BMI=18-24
Exclusion criteria:
Smoking and Drug Use
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are selected based on Entry and Exit Criteria. After Obtaining informed Consent from the Patients, they are assigned to the Two Groups of p and v Using the Random quadratic Block Method. In this Method, a Table of 50 Letters of the Letters p and v is prepared and then, to observe the Random Allocation Hiding, each of These Letters is enclosed in a sealed Envelope, Respectively. After Closing the Door, each Envelope on it is numbered, in the Order of the original Table. After Selecting a qualified Patient, the Envelope for that Patient is opened and, based on the Letters inside, the Patient is assigned to one of the Two Groups.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This Research is a Triple blind Study. The Patients Undergoing general Anesthesia prior to the Intervention and are blinded. The trained Person who measures the Cuff Pressure and Air Leakage is blinded by Covering the Ventilator and uncertain Ventilator Mode. The Data Analyzer is blinded by the Coding of the Two Study Groups (P and v) to the Groups (A and B).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahroud Univercity of Medical Sciences
Street address
Shahroud University of Medical Sciences, Hafte-Tir Sq., Tehran Street
City
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Province
Semnan
Postal code
3614773955
Approval date
2018-12-30, 1397/10/09
Ethics committee reference number
IR.SHMU.REC.1397.174

Health conditions studied

1

Description of health condition studied
Changes in Cuff Pressure and Air Leakage around the Endotracheal Tube
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Changes in Intracuff Pressure of the Endotracheal Tube
Timepoint
At the Beginning of the Study (before the Intervention) and 10, 20 and 30 Minutes after Applying the Volume controlled or Pressure controlled Ventilation Mode on the Ventilator
Method of measurement
Using the German VBM Manometer (with a Measurement Range of 0-120 CmH2o).

2

Description
Co2 Leakage Changes (as an Indicator of Air Leakage) around the Cuff of the Endotracheal Tube
Timepoint
Measuring the aAmount of Co2 in the Supraglutic Space at the Beginning of the Study (before the Intervention) and 10, 20, and 30 Minutes after Applying the Ventilation Mode, volume controlled or pressure controlled on the Ventilator
Method of measurement
Using the Sazgan Gostar Capnograph, in the Superglot Space will be measured

Secondary outcomes

empty

Intervention groups

1

Description
Intervention: In Group P (Intervention), after Connecting the Patient to the Ventilator, the Pcv Mode (as an Intervention of this Study) will be used for Mechanical Ventilation during Anesthesia. This Mode is set on the Ventilator and the Airway Pressure is adjusted to reach a Tidal Volume of 7ml / kg.
Category
Treatment - Devices

2

Description
Control group: In Group v (Control), the Routine Method is used for Mechanical Ventilation of Patients during Anesthesia. In this Group of Patients, vcv Mode, which is a Routine Ventilation Mode, will be activated on the Ventilator and the Tidal Volume of 7 ml / kg will be adjusted on the Ventilator.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahroud 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
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Position
Student
Latest degree
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Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available