

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 University 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 Amount of Co2 in the Supraglottic 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 7 ml / 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

Ali Abbasi

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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

Shahroud University of Medical Sciences

Full name of responsible person

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Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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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