

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of The Effects of Sevoflurane and Total Intravenous Anaesthesia (TIVA) on Pulmonary Function Tests (PFT)

Protocol summary

Study aim

Comparison of TIVA and Sevoflurane on changing the results of Pulmonary Function Test (PFT) in patients undergoing inguinal hernia surgery

Design

In this interventional study, 18-65 year old patients, with ASA class 1 and 2 who undergo inguinal herniation surgery in the supine position, randomly assign to into two groups consisted of 55 people. Randomization will be done through using permuted blocks.

Settings and conduct

During this practical interventional study, patients who meet inclusion criteria will randomly dividing into two 55-member groups. Before starting anesthesia, both groups undergoing spirometry at Kashan Naghavi Hospital and then under the same conditions, they will be under anesthesia induction and monitoring. Then with single-blind way, one group will be undergoing propofol infusion and the second one will get anesthesia with sevoflurane. Finally, after being aware completely, patients will perform the spirometry test again in the recovery room and the recorded results will be analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with ASA class 1 & 2, aged 18 to 65 years old, Candidate for unilateral inguinal hernia surgery. Exclusion criteria: severe cardiovascular diseases, the patient with COPD, chest deformity, liver and kidney failure, and BMI more than 35.

Intervention groups

In this study, The subjects of each group, will receive general anesthesia induction at the same condition, and then, they will be divided into two groups of 55 members. In the first group those patient receiving intravenous anesthesia (TIVA), will be infused by propofol and in the second group, anesthesia will be maintained with sevoflurane and N₂O until the end of the operation.

Main outcome variables

Forced Vital Capacity (FVC); Forced Expiratory Volume in First second (FEV₁); FEV₁ / FVC.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180108038263N1**

Registration date: **2018-05-29, 1397/03/08**

Registration timing: **retrospective**

Last update: **2018-05-29, 1397/03/08**

Update count: **0**

Registration date

2018-05-29, 1397/03/08

Registrant information

Name

Leila Mehrzad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0026

Email address

mehrzad-l@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-04-19, 1397/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of The Effects of Sevoflurane and Intravenous Anaesthesia (TIVA) on Pulmonary Function Tests(PFT)		Name of ethics committee Ethics committee of Kashan University of Medical Sciences	
Public title Comparison of The Effects of Sevoflurane and Total Intravenous Anaesthesia on postoperative Pulmonary Function Tests		Street address Kashan University of Medical Sciences, Pezeshk Blvd	
Purpose Prevention		City Kashan	
Inclusion/Exclusion criteria Inclusion criteria: Patients with American Society Anesthesia (ASA) grade 1 & 2, Being at the age of 18 to 65 years old, candidate for unilateral inguinal hernia surgery. Exclusion criteria: Patients with severe cardiovascular disease Patients with Chronic Obstructive Pulmonary Diseases(COPD) Patients with chest deformity Patients with kidney and liver failure Patients with Body Mass Index(BMI) greater than 35		Province Isfahan	
Age From 18 years old to 65 years old		Postal code 8715988141	
Gender Both		Approval date 2017-10-19, 1396/07/27	
Phase 3		Ethics committee reference number IR.kaums.mednt.rec1396066	
Groups that have been masked Participant		Health conditions studied 1 Description of health condition studied lung function tests ICD-10 code ICD-10 code description	
Sample size Target sample size: 110 More than 1 sample in each individual Number of samples in each individual: 2 Before and after operation, spirometry is performed for each patient.		Primary outcomes 1 Description Forced Expiratory Volum (FEV1) Timepoint Prior the onset of anesthesia, after the operation in recovery room Method of measurement Spirometer	
Randomization (investigator's opinion) Randomized		2 Description Forced Vital Capacity (FVC) Timepoint Prior the onset of anesthesia, after the operation in recovery room Method of measurement Spirometer	
Randomization description Permuted blocked randomization,sampling in each group is based on quadruple blocks obtained from random codes extracted from random number table.		3 Description FEV1/FVC Timepoint Prior the onset of anesthesia, after the operation in recovery room Method of measurement Spirometer	
Blinding (investigator's opinion) Single blinded		Secondary outcomes empty	
Blinding description Study is single blind, After entering the study, patients are randomized to either Sevoflurane or Propofol group.			
Placebo Not used			
Assignment Parallel			
Other design features			
Secondary Ids empty			
Ethics committees 1 Ethics committee			

Intervention groups

1

Description

First Intervention group: with Conventional Anesthesia Method the anesthesia will be administered by following drugs, including Midazolam 2 Milligram(mg) Intravenous (IV),Fentanyl 2 microgram per Kilogram(μ /kg), Propofol 2/5 milligram per kilogram(mg/kg) IV, Atracurium 0.5 mg/kg IV, and anesthesia will be maintained with 1-1.5 Minimum Alveolar Concentration(Mac) sevoflurane and Nitric Oxide (N₂O) 70% and Oxygen (O₂) 30%.each Mac of Sevofloran is 3%

Category

Treatment - Drugs

2

Description

Second Intervention group: with Conventional Anesthesia Method, anesthesia will be administered by following drugs, including Midazolam 2 mg IV, Fentanyl 2 μ /kg, Propofol 2/5 mg/kg IV, Atracurium 0.5 mg/kg IV, and anesthesia will be maintained with infusion of 100 ug/kg/min propofol.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Naghavi hospital

Full name of responsible person

Leila Mehrzad

Street address

Shahid Rajaee Street

City

Kashan

Province

Isfahan

Postal code

8713743444

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

Street address

Vice chancellor for research, Medical School, 5th km

of Ghotbe Ravandi Blvd

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hamidi_gh@kaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Leila Mehrzad

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Shahid Beheshti hospital, 5th km of Ghotbe Ravandi Blvd.

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hajijaafari Mohammad Ali

Position

professor

Latest degree

Specialist

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Resident in training

Latest degree

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Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is 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

Title and more details about the data/document

Only the details of the original outcome are shared.

When the data will become available and for how long

Immediately after printing the results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Any statistical analysis on data is allowed.

From where data/document is obtainable

To access the data, people should send name, degree of education, and intended university to this email address: l.mehrzad.20002@gmail.com

What processes are involved for a request to access data/document

To access the data, people should send name, degree of education, and intended university to this email address: l.mehrzad.20002@gmail.com

Comments