Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of The Effects of Sevoflurane and Itotal ntravenous 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 permutated 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 recieve general anesthesia induction at the same condition, and then ,they will be devided into two groups of 55 members.In the first group those pateint recieving intravenous anesthesia(TIVA), will be infused by propofol and in the second group,anesthesia will be maintained with sevoflorane and N2O until the end of the operation.

Main outcome variables

Forced Vital Capacity (FVC); Forced Expiratory Volum 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

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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 Itotal ntravenous Anaesthesia (TIVA) on Pulmonary Function Tests(PFT)

Public title
Comparison of The Effects of Sevoflurane and Total Intravenous Anaesthesia on postoperative Pulmonary Function Tests
Purpose
Prevention
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
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

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.
Randomization (investigator's opinion)
Randomized
Randomization description
Permuted blocked randomization,sampling in each group is based on quadruple blocks obtained from random codes extracted from random number table.
Blinding (investigator's opinion)
Single blinded
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
Name of ethics committee
Ethics committee of Kashan University of Medical Sciences
Street address
Kashan University of Medical Sciences, Pezeshk Blvd
City
Kashan
Province
Isfehan
Postal code
8715988141
Approval date
2017-10-19, 1396/07/27
Ethics committee reference number
IR.kaums.mednt.rec1396066

Health conditions studied

1

Description of health condition studied
lung function tests
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Forced Expiratory Volum (FEV1)
Timepoint
Prior the onset of anesthesia, after the operation in recovery room
Method of measurement
Spirometer

2

Description
Forced Vital Capacity (FVC)
Timepoint
Prior the onset of anesthesia, after the operation in recovery room
Method of measurement
Spirometer

3

Description
FEV1/FVC
Timepoint
Prior the onset of anesthesia, after the operation in recovery room
Method of measurement
Spirometer

Secondary outcomes

empty

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
Ŝhahid Rajaee Street

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Kashan

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Isfehan

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8713743444

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mehrzad-l@kaums.ac.ir

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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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

Street address
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

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Leila Mehrzad

Position
Resident in training

Latest degree
Medical doctor

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 accsess the data,people should send name,degree of education,and intended university to this email adress:l.mehrzad.20002gmail.com

What processes are involved for a request to access data/document
To accsess the data,people should send name,degree of education,and intended university to this email adress:l.mehrzad.20002gmail.com

Comments