

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Clinical trial comparing the hemodynamic changes in two methods of complete intravenous and inhalation anesthetics in patients candidate for laparoscopy peritoneal catheterization

Protocol summary

Study aim

Evaluate the hemodynamic changes in two methods of complete intravenous and inhalation anesthesia in patients candidate for laparoscopy peritoneal catheterization

Design

Intervention 1: In the anesthetic inhalation group, for induction, sodium thiopental 4 mg/kg used. Isoflurane 1-2.1% used for maintenance anesthesia. Intervention 2: In the complete intravenous anesthetic group, for induction, Etomidate 3.0 µg/kg is used. For maintenance of anesthesia, Etomidate 100 µg/kg for the first 10 minutes after induction and followed by 20 µg/kg for up to 10 minutes until the end of the surgery used. Clinical trial phase: 3.

Settings and conduct

The aim of the study is to evaluate the hemodynamic changes in two methods of complete intravenous and inhalation anesthesia in patients candidate for laparoscopy peritoneal catheterization. The study conducted in the Emam Khomeini hospital of Tehran city. Seventy patients were randomly assigned into two groups of complete anesthesia and inhalation anesthesia using random block method. In this study, the patients, measuring the outcomes of study participants (researchers) or Data Monitoring Committee (analyzers) of the patients unaware of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 30 to 70 years; ASA class III and IV, exclusion criteria: Complications during or after laparoscopic surgery.

Intervention groups

Intervention 1: In the anesthetic inhalation group, for induction, sodium thiopental 4 mg/kg used. Isoflurane 1-2.1% used for maintenance anesthesia. Intervention 2: In the complete intravenous anesthetic group, for induction, Etomidate 3.0 µg/kg is used. For maintenance

of anesthesia, Etomidate 100 µg/kg for the first 10 minutes after induction and followed by 20 µg/kg for up to 10 minutes until the end of the surgery used.

Main outcome variables

Hemodynamic changes include systolic and diastolic blood pressure, arterial blood pressure and heart rate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070934978N1**

Registration date: **2017-08-17, 1396/05/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-19, 1396/12/28**

Update count: **1**

Registration date

2017-08-17, 1396/05/26

Registrant information

Name

Mojgan Rahimi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01
Expected recruitment end date
 2017-08-22, 1396/05/31
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Clinical trial comparing the hemodynamic changes in two methods of complete intravenous and inhalation anesthetics in patients candidate for laparoscopy peritoneal catheterization

Public title
 Comparison of hemodynamic changes in both intravenous and inhalation anesthetics

Purpose
 Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Age between 30 to 70 years ASA class III and IV
Exclusion criteria:
 Complications during or after laparoscopic surgery

Age
 From **30 years** old to **70 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
 Target sample size: **72**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Random method: Block, Random unit: individual, Random Tool: Random Block 4

Blinding (investigator's opinion)
 Triple blinded

Blinding description
 In this study, the patients, measuring the outcomes of study participants (researchers) or Data Monitoring Committee (analyzers) of the patients unaware of intervention.

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshvarz Blvd

City

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Province

Tehran

Postal code

1345789522

Approval date

2016-12-26, 1395/10/06

Ethics committee reference number

IR.TUMS.VCR.REC.1395.1316

Health conditions studied

1

Description of health condition studied

End Stage Renal Disease

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

First visit the operating room, after the induction, after intubation, before the gas injection into the abdominal cavity, after the injection of the gas into the abdominal cavity and then in the recovery room

Method of measurement

Noninvasive blood pressure monitor

2

Description

Diastolic blood pressure

Timepoint

First visit the operating room, after the induction, after intubation, before the gas injection into the abdominal cavity, after the injection of the gas into the abdominal cavity and then in the recovery room

Method of measurement

Noninvasive blood pressure monitor

3

Description

Mean arterial blood pressure

Timepoint

First visit the operating room, after the induction, after intubation, before the gas injection into the abdominal cavity, after the injection of the gas into the abdominal cavity and then in the recovery room

Method of measurement

Noninvasive blood pressure monitor

Secondary outcomes**1****Description**

Heart rate per minute

Timepoint

First visit the operating room, after the induction, after intubation, before the gas injection into the abdominal cavity, after the injection of the gas into the abdominal cavity and then in the recovery room

Method of measurement

Monitor

Intervention groups**1****Description**

Control group: In the complete intravenous anesthetic group, for induction, Etomidate 3.0 µg/kg is used. For maintenance of anesthesia, Etomidate 100 µg/kg for the first 10 minutes after induction and followed by 20 µg/kg for up to 10 minutes until the end of the surgery is used.

Category

Other

2**Description**

Intervention group: In the anesthetic inhalation group, for induction, sodium thiopental 4 mg/kg is used. Isoflurane 1-2.1% is used for maintenance anesthesia.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital of Tehran University of Medical Sciences

Full name of responsible person

Mojgan Rahimi

Street address

Imam Khomeini Hospital, Keshavarz Blv

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mrahimi@tums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Yunesian

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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

Vice chancellor for research, Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Razieh Erfani

Position

Student, Anesthesiology Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mojgan Rahimi

Position

Faculty member/Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Razieh Erfani

Position

Anesthesiology Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Web page address**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

Journals of medical sciences

When the data will become available and for how long

From 2019

To whom data/document is available

Researchers working in academia, science and industry

Under which criteria data/document could be used

None

From where data/document is obtainable

Researchers

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

Researchers

Comments