Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Clinical trial comparing the homodynamic 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)

Phone

+98 84426391

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mrahimi@tums.ac.ir

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 homodynamic 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

Tehran

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 mµg/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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Tehran
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134567222
Phone
+98 21 8805 3766
Email
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
Street address
Tehran University of Medical Sciences, Keshavarz Blvd
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Postal code
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Phone
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Email
mrahimi@tums.ac.ir
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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Person responsible for scientific inquiries

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Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Tehran University of Medical Sciences
Full name of responsible person
Razieh Erfani
Position
Anesthesiology Assistant
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Medical doctor
Other areas of specialty/work
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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
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