Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 2026

Comparison of Postoperative Nausea and Vomiting (PONV) with Total Intravenous Anesthesia (TIVA) versus Inhalational Anesthesia in patients undergoing Elective Laparoscopy in Imam Khomeini Hospital Complex-Tehran (IKHC)

Protocol summary

Study aim

This study was designed to compare the effect of two methods of anesthesia (total intravenous anesthesia with propofol and inhalational anesthesia with isoflurane) on postoperative nausea and vomiting in patients undergoing elective laparoscopy.

Design

Randomized, single-blinded, parallel, clinical trial, phase 3

Settings and conduct

Randomization on an individual level using 4 number blocks created in excel software. Allocation concealment has been carried out. Given the patient's anesthesia after receiving the induction which is identical in both groups, the patient is blind to the type of anesthesia, due to the apparent difference between the two types of anesthesia (inhaler jet mask and intravenous injections). Anesthesiologist (PI) and researcher are not blind to the type of anesthesia and the study is conducted in a single-blinded manner. Data collectors and data analysts have also been blinded. This is study was conducted in Imam Khomeini Hospital Complex. The incidence and severity of nausea and vomiting was evaluated and recorded at 0, 6, 12, and 24 hours after the surgery.

Participants/Inclusion and exclusion criteria

All patients aged 18-65, with ASA class I and II who underwent elective laparoscopy, were included. In the case of emergency surgery, the history of motion sickness or PONV, Positive drug Allergy history, use of anti-emetic drug or unwillingness of the patient, the case was excluded.

Intervention groups

. In the inhalation group, Isoflurane %1.5-1.7 in combination with 1cc Fentanyl and 1cc Atracurium were used every 45-60 minutes during the operation. In the intravenous group, 50cc of Propofol 1% was combined with 1-2cc of Remifentanil and was intravenously infused at the speed of 15-20cc/hr

Main outcome variables

Postoperative nausea and severity in 0, 2, 6, 12, 24 hours after surgery Postoperative vomiting and severity at 0, 2, 6, 12, 24 hours after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190904044685N2**
Registration date: **2019-10-12, 1398/07/20**
Registration timing: **retrospective**

Last update: **2019-10-12, 1398/07/20**
Update count: **0**

Registration date

2019-10-12, 1398/07/20

Registrant information

Name

kasra karvandian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2620 0287

Email address

k.karvandian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date
2018-12-22, 1397/10/01

Actual recruitment start date
2019-01-20, 1397/10/30

Actual recruitment end date
2019-05-20, 1398/02/30

Trial completion date
2019-07-23, 1398/05/01

Scientific title
Comparison of Postoperative Nausea and Vomiting (PONV) with Total Intravenous Anesthesia (TIVA) versus Inhalational Anesthesia in patients undergoing Elective Laparoscopy in Imam Khomeini Hospital Complex-Tehran (IKHC)

Public title
Postoperative nausea and vomiting in patients undergoing elective laparoscopy; comparison of total intravenous anesthesia versus inhalational anesthesia; a randomized clinical trial

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
ASA class I ASA class II Elective laparoscopy

Exclusion criteria:
History of motion sickness History of PONV Positive drug Allergy history Unwillingness of the patient

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
Actual sample size reached: **122**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization on an individual level using 4 number blocks created in excel software. Allocation concealment has been carried out.

Blinding (investigator's opinion)
Single blinded

Blinding description
Given the patient's anesthesia after receiving the induction which is identical in both groups, the patient is blind to the type of anesthesia, due to the apparent difference between the two types of anesthesia (inhaler jet mask and intravenous injections). Anesthesiologist (PI) and researcher are not blind to the type of anesthesia and the study is conducted in a single-blinded manner. Data collectors and data analysts have also been blinded.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Imam Khomeini Hospital Complex - Tehran University of Medical Sciences

Street address
Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
1419733141

Approval date
2018-07-03, 1397/04/12

Ethics committee reference number
IR.TUMS.IKHC.REC.1397.075

Health conditions studied

1

Description of health condition studied
Postoperative nausea and vomiting

ICD-10 code
K91.0

ICD-10 code description
Vomiting following gastrointestinal surgery

Primary outcomes

1

Description
Incidence and severity of postoperative nausea and vomiting

Timepoint
0, 2, 6, 12, 24 hours after surgery

Method of measurement
Standardized questionnaire, Verbal/Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Total intravenous anesthesia. In the intravenous group, 50cc of Propofol 1% was combined with 1-2cc of Remifentanil and was intravenously infused at the speed of 15-20cc/hr. Depending on patients' needs and duration of the surgery, the dosage altered to ¬±5cc.

Category
Treatment - Drugs

2

Description
Control group: Inhalational anesthesia. In the inhalation group, Isoflurane %1.5-1.7 in combination with 1cc Fentanyl and 1cc Atracurium were used every 45-60 minutes during the operation.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital Complex

Full name of responsible person
Kasra Karvandian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
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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
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
Kasra Karvandian

Position
Associate professor

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available