

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 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 Remifentanyl 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 Remifentanyl and was intravenously infused at the speed of 15-20cc/hr. Depending on patients' needs and duration of the surgery, the dosage altered to ± 5 cc.

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

Street address

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karvandian@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ahmad Esmailzadeh

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vcr@tums.ac.ir

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

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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

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Latest degree

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Other areas of specialty/work

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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