

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of Post Operative Nausea and Vomiting (PONV) with Total Intravenous Anesthesia (TIVA) versus Inhalational Anesthesia in patients undergoing Elective Laparotomy 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 vs inhalational anesthesia) on postoperative nausea and vomiting after elective abdominal laparotomic surgery

Design

phase 3, Parallel-group, single-blind, randomized clinical trial.

Settings and conduct

randomization on an individual level using 4 number blocks created in excel. allocation concealment was carried out. Given the patients' anesthesia after receiving the induction, the patient is blind to the kind of anesthesia. Due to the apparent difference between the two types of anesthesia (the mask vs IV medication) the anesthesiologist was not blind to the type of anesthesia, so the study was conducted in a single-blinded manner. The personals in charge of gathering and analyzing the data were blinded using codes for groups, to the identity of the patients. The study was conducted in Imam Khomeini Hospital Complex, Tehran. The incidence and severity of patients' nausea and vomiting were evaluated and recorded at 0, 6, 12 and 24 hours after the surgery.

Participants/Inclusion and exclusion criteria

Patients aged 18-65, with ASA class I and II who underwent elective abdominal laparotomic surgery were included. In the case of the history of PONV, Positive drug Allergy history or unwillingness of the patient, the patients were excluded.

Intervention groups

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/hour. Depending on the patients' need the dosage was altered by ± 5 cc. In the inhalation group, Isoflurane % 1.5 -% 1.7 in combination with 1cc Fentanyl and 1cc Atracurium

was used every 45-60 minutes.

Main outcome variables

Occurrence and severity of post-operative nausea in 0, 6, 12, 24 hours post-surgery Occurrence and severity of vomiting in 0, 6, 12, 24 hours post-surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190904044685N1**

Registration date: **2019-10-06, 1398/07/14**

Registration timing: **retrospective**

Last update: **2019-10-06, 1398/07/14**

Update count: **0**

Registration date

2019-10-06, 1398/07/14

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 Post Operative Nausea and Vomiting (PONV) with Total Intravenous Anesthesia (TIVA) versus Inhalational Anesthesia in patients undergoing Elective Laparotomy in Imam Khomeini Hospital Complex-Tehran (IKHC)

Public title

Comparison of Post-Operative Nausea and Vomiting (PONV) with Total Intravenous Anesthesia (TIVA) versus Inhalational Anesthesia in elective laparotomic abdominal surgery; A Randomized Clinical Trial

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Elective abdominal laparotomy asa class I asa class II

Exclusion criteria:

hypersensitivity reaction patient's unwillingness to continue history of PONV

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: **105**

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 patients' anesthesia after receiving the induction-which is identical in both groups-the patient is blind to the kind of anesthesia. Due to the apparent difference between the two types of anesthesia (the mask for inhalation group and IV medication for TIVA) the anesthesiologist (PI) and the researcher are not blind to the type of anesthesia received by the patient, so the study is conducted in a single-blinded manner. The personals in charge of gathering and analyzing the data were blinded using codes for groups, to the identity of

patients' using codes.

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 Blv

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2018-07-03, 1397/04/12

Ethics committee reference number

IR.TUMS.IKHC.REC.1397.076

Health conditions studied**1****Description of health condition studied**

post operative nausea and vomiting

ICD-10 code

k91

ICD-10 code description

Vomiting following gastrointestinal surgery

Primary outcomes**1****Description**

Nausea and vomiting, occurrence & severity

Timepoint

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

Method of measurement

standardized questionnaire, verbal and visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Total IntraVenous Anesthesia

Category

Treatment - Drugs

2

Description

Control group: inhalational anesthesia

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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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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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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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