Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Remifentanil and was intravenously infused at the speed of 15-20cc/hour. Depending on the patients' need the dosage was altered by ±5cc. 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)

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+98 21 2620 0287

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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Email
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Web page address
https://www.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
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Position
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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