Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the relationship between end tidal carbon dioxide pressure and the incidence of severe nausea and vomiting after general anesthesia in laparoscopic cholecystectomy

Protocol summary

Study aim
Evaluation of the relationship between end-expiratory carbon dioxide pressure and the incidence of severe nausea and vomiting after general anesthesia in laparoscopic cholecystectomy

Design
Randomized three-way parallel blind group clinical trial on 88 patients Randomized allocation software was used for randomization

Settings and conduct
The operating room and recovery ward of Al-Zahra and Kashani hospitals are blindfolded with a researcher, outcome assessor and participant.

Participants/Inclusion and exclusion criteria
88 candidates for laparoscopic cholecystectomy with ASA1,2 in the age group of 18-65 years No history of motion sickness and no history of postoperative nausea and vomiting as well as insensitivity to anesthesiaExclusion criteria are: severe intraoperative hemodynamic disorders that lead to a change in anesthesia and failure to complete the questionnaire after surgery. Also in case of allergy to anesthetic drugs in those who are undergoing surgery for the first time If the operation lasts longer, it will be removed from the study after 2 hoursNon-admission: Patients with ASA 3 and 4 and severe underlying diseases such as heart failure, COPD, ESRD

Intervention groups
Intervention group: The first group of people undergoing laparoscopic cholecystectomy with a capnograph to maintain the level of carbon dioxide at the end of exhalation between 40-40 mm Hg,The second group of people undergoing laparoscopic cholecystectomy with a capnograph to maintain the level of carbon dioxide at the end of exhalation between 40-40 mm Hg

Main outcome variables
Frequency and severity of nausea and vomiting after surgery. Severe pain. Blood pressure. Antiemetic drug. Drugs

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210503051169N1**
Registration date: **2021-07-17, 1400/04/26**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-17, 1400/04/26**
Update count: **0**

Registration date
2021-07-17, 1400/04/26

Registrant information

Name
mahdi mianji

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3661 7278

Email address
mahdimianji313@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-16, 1400/04/25

Expected recruitment end date
2021-08-16, 1400/05/25

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the relationship between end tidal carbon dioxide pressure and the incidence of severe nausea and vomiting after general anesthesia in laparoscopic cholecystectomy

Public title

Evaluation of the relationship between end tidal carbon dioxide pressure and the incidence of severe nausea and vomiting after general anesthesia in laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

88 candidates for laparoscopic cholecystectomy with ASA1,2 in the age group of 18-65 years

Exclusion criteria:

Patients with ASA 3 and 4 Severe underlying disease such as heart failure, COPD, ESRD History of motion sickness and history of postoperative nausea and vomiting Allergy to anesthesia

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Random sequence (blocking) is generated by the help of Excel software and blocks of four are used to equalize the two groups so that the groups 1 and 2 of each person included in the study, can be determined randomly and equally. The blocks of four are separated from the samples and placed in the block randomly by the Excel software of group A or B. At the end, it is determined which letter represents the intervention group 1 and 2.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The participant (patient) is not aware of which group they are in. The clinical caregiver adjusts the capnograph to one of two groups according to the randomization. Without knowing the grouping of people after the operation, the evaluator completes the outcome with a questionnaire without personal information. The questionnaires are given to the researcher in the form of A and B who do not know which is the first or second group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

No.87, 3rdAlley, Golestan, Apadana St,1stAlley, Feiz square, Isfahan, Iran

City

Esfahan

Province

Isfehan

Postal code

8165636761

Approval date

2021-04-30, 1400/02/10

Ethics committee reference number

IR.MUI.MED.REC.1400.080

Health conditions studied

1

Description of health condition studied

Evaluation of the relationship between end tidal carbon dioxide pressure and the incidence of severe nausea and vomiting after general anesthesia in laparoscopic cholecystectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Determining and comparing the frequency of postoperative nausea and vomiting in two groups with expiratory end carbon dioxide pressure of 40-40 and 40-45

Timepoint

Every 15 minutes in recovery 2, 4 and 6 hours after surgery

Method of measurement

Through a questionnaire

2

Description

Determining and comparing the average dose of antiemetic drugs in two groups with expiratory carbon dioxide pressure of 40-40 and 45-40

Timepoint

At recovery time 2, 4 and 6 hours after surgery

Method of measurement

Through a questionnaire

3

Description

Determining and comparing the average dose of opioids in two groups with expiratory end carbon dioxide pressure of 35-40 and 40-45

Timepoint

At recovery time 2, 4 and 6 hours after surgery

Method of measurement

Through a questionnaire

4

Description

Determination and comparison of pain intensity during recovery in two groups with expiratory end of carbon dioxide pressure of 35-40 and 40-45

Timepoint

2, 4 and 6 hours after surgery

Method of measurement

Based on VAS

5

Description

Determining and comparing the average level of patient satisfaction in two groups with expiratory end carbon dioxide pressure of 40-40 and 45-40

Timepoint

In 6 hours after surgery

Method of measurement

Based on VAS

Secondary outcomes

1

Description

Determination and comparison of mean arterial blood pressure, oxygen saturation and heart rate in two groups with expiratory end carbon dioxide pressure of 40-40 and 45-40

Timepoint

Basically then every half hour during surgery and recovery

Method of measurement

Through a questionnaire

2

Description

Determining and comparing the duration of anesthesia and the duration of recovery surgery (duration of extubation) in two groups with expiratory end carbon dioxide pressure of 35-40 and 40-45

Timepoint

end of surgery

Method of measurement

Through a questionnaire

Intervention groups

1

Description

Intervention group: The first group of people undergoing laparoscopic cholecystectomy, which is maintained by a capnograph of the end-tidal carbon dioxide level between 35-40 mm Hg.

Category

Treatment - Other

2

Description

Intervention group: The second group of people underwent laparoscopic cholecystectomy, which is maintained by a capnograph of the end-tidal carbon dioxide level between 40-45 mm Hg.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital of Isfahan

Full name of responsible person

Dr.Khosro Naghibi

Street address

Sefeh Blvd, alzahra hospital

City

Esfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

alzahra@mui.ac.ir

2

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

DR.Khosro Naghibi

Street address

Kashani St, Kashani Hospital

City

Esfahan

Province

Isfehan

Postal code
8183983434
Phone
+98 31 3233 0091
Email
kashani@mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr.Khosro Naghibi
Street address
Hezar Jerib St., Isfahan University of Medical Sciences
City
Esfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
jims@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
40
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
Esfahan University of Medical Sciences
Full name of responsible person
Dr.Khosro Naghibi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
No. 17, Hezar Jarib St., Sepahan Alley, 6th St.
City
Esfahan
Province
Isfehan
Postal code
8175675333
Phone
+98 31 3670 2548
Email
khnaghibi@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr.Khosro Naghibi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
No. 17, Hezar Jarib St., Sepahan Alley, 6th St.
City
Esfahan
Province
Isfehan
Postal code
8175675333
Phone
+98 31 3670 2548
Email
khnaghibi@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr.Khosro Naghibi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
No. 17, Hezar Jarib St., Sepahan Alley, 6th St.
City
Esfahan
Province
Isfehan
Postal code
8175675333
Phone
+98 31 3670 2548
Email

khnaghibi@gmail.com

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
No - There is not 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
Only registered marks can be published without mentioning the names of the participants
When the data will become available and for how long
6 months after printing the results
To whom data/document is available
It will be available only to researchers working in academic and scientific institutions
Under which criteria data/document could be used
Written request by e-mail and approval of the Vice Chancellor for Research
From where data/document is obtainable
By correspondence with the responsible author via email
What processes are involved for a request to access data/document
The applicant will be notified within one week of receiving the consent from the university,Maximum access takes 10 business days
Comments