Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of depth of anesthesia on pain after surgery in laparascopic cholesystectomy

Protocol summary

Summary

The aim of this study is to evaluate the effect of depth of anesthesia on pain after laparoscopic cholecystectomy. 66 patients undergoing laparoscopic cholesystectomy referred to Hazrat Rasool Akram Hospital as a randomized, double-blind,without controlled with placebo and without a trial phase with using the file number and in parallel are divided into two groups. Patients should be aged between 18 and 65 years and should be have ASA I ir II and patients with operated for more than three hours or conversion to laparotomy laparoscopic surgery were excluded. In the first group, BIS between 35 and 45 (Group L)is maintained and in the second group (Group H) BIS between 45 and 55 is maintained with drug using. At the end of surgery, drug consumption during operation and lenth of opertaion are recorded. The amount of pain of patients is recorded with using of VAS score in recovery and post-operative hours. The need for opioids during 24 hours after operation and the rate of nausea and vomiting after surgery and patient satisfaction also be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011412642N25**
Registration date: **2017-01-24, 1395/11/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-01-24, 1395/11/05

Registrant information

Name

Majid Golestani Eraghi

Name of organization / entity

Shahid Beheshti University Of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of depth of anesthesia on pain after surgery in laparascopic cholesystectomy

Public title

The effect of depth of anesthesia on pain after surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patient candidated for elective laparascopic cholesystectomy; patient with ASA I or II; Lack of malignancy or seizures; Lack of auditory problem; BMI<35; Lack of heart, pulmonary, liver and kidney failure; Lack of uncontrolled systemic disease; Lack of addiction; Lack of chronic pain and/or with any analgesic drug.Exclusion criteria: Prolongation of action

for more than three hours; Conversion of laparoscopic surgery to laparotomy; patient death.

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
patients with due attention to file number pair and odd, were randomely divided into two groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice chancellor for research, Iran University of Medical Sciences

Street address
Vice chancellor for research of Iran University of Medical Sciences, Hemmat Highway

City
Tehran

Postal code

Approval date
2015-06-24, 1394/04/03

Ethics committee reference number
ir.iums.res.1394.9211174020

Health conditions studied

1

Description of health condition studied
general anesthesia

ICD-10 code
Y84

ICD-10 code description
Other medical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description
Heart rate

Timepoint
during surgery, before and after that

Method of measurement
with pulse oxymeter device and according to beat per minute

2

Description
need to analgesic drug

Timepoint
during 24 hours after surgery

Method of measurement
according to miligeram

3

Description
amount of pain

Timepoint
in recovery and 8,16 and 24hours after surgery

Method of measurement
with using of VAS score

4

Description
systolic and diastolic blood pressure

Timepoint
during surgery, before and after that

Method of measurement
Non-invasive barometer in mm Hg

Secondary outcomes

1

Description
amount of nausea and vomitting

Timepoint
during 24 hours after surgery

Method of measurement
according to severity and score 0 to 3

2

Description
duration of surgery

Timepoint
from start of surgery to start of recovery

Method of measurement
according to minute

Intervention groups

1

Description
In the first group (L group) after induction of anesthesia, anesthesia in order to maintain BIS between 35 and 45, propofol with dose of 75 to 150 micrograms per kilogram of body weight and remifentanil with dose of 0.1 to 0.3 micrograms per kilogram of body weight are used

Category
Prevention

2

Description
In the first group (H group) after induction of anesthesia, anesthesia in order to maintain BIS between 35 and 45, propofol with dose of 75 to 150 micrograms per kilogram of body weight and remifentanil with dose of 0.1 to 0.3 micrograms per kilogram of body weight are used

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrat Rasool Hospital

Full name of responsible person
Poopak Rahimzadeh

Street address
Satarkhan Ave

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person
Seyed Alijavad Musavi

Street address
Vice chancellor for research of Iran University of Medical Sciences, Hemmat Highway

City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for research, Iran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Anesthesiology group of Iran University of Medical Science

Full name of responsible person
Poopak Rahimzadeh

Position
Fellowship in pain

Other areas of specialty/work

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Hazrat Rasool Hospital, Satarkhan Ave

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Poopak Rahimzadeh

Position
Fellowship in pain

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)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty