

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Compare the effect of TIVA and isoflurane on the activity of liver enzymes in patients undergoing laparoscopic cholecystectomy

Protocol summary

Study aim

Comparison the effect of Tiva anesthesia with isoflurane on liver enzymes activity in patients undergoing laparoscopic cholecystectomy

Design

The study is a randomized double-blind clinical trial

Settings and conduct

Imam Ali Hospital of Bojnourd, North Khorasan University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria: signing informed consent to participate in the study; has no history of anesthesia in the past 6 months; the patient's age is between 18 and 70 years old; be in accordance with ASA grade one or two grade anesthesia; no history of specific drug use; does not have a specific underlying disease such as liver disease.

Exclusion criteria: the patient needs more pharmacotherapy during acne surgery; patients may require cardiopulmonary resuscitation during surgery; inability to exit the endotracheal tube at the end of surgery; intraoperative bleeding; laparoscopic transformation to open excessive liver damage during surgery and surgeon manipulation.

Intervention groups

Atracurium (0.5 mg / kg) and propofol (2 mg / kg) are used to induce anesthesia. After 3 minutes of hyperventilating and intubation, anesthesia was administered in the first group of isoflurane 1.2 mg and in the second group propofol 100 µg / kg with remifenil. (0.1 mcg for body weight per minute) will be used.

Surgery will then be performed on all patients by a laparoscopic specialist with a qualified general surgery specialist who is blind to the drugs. After surgery and discontinuation of anesthesia, a reversal of injection (neostecmin plus atropine) will be performed for all patients with the aim of restoring the patient's muscle strength and spontaneous ventilation.

Main outcome variables

Hepatic Enzyme ALT; Hepatic Enzyme AST; Hepatic

Enzyme ALP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200122046216N1**

Registration date: **2020-02-10, 1398/11/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-10, 1398/11/21**

Update count: **0**

Registration date

2020-02-10, 1398/11/21

Registrant information

Name

Mahdieh Dartomi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3223 3231

Email address

m.dartomi@nkums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-20, 1398/04/29

Expected recruitment end date

2020-02-18, 1398/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Compare the effect of TIVA and isoflurane on the activity of liver enzymes in patients undergoing laparoscopic cholecystectomy

Public title
Compare the effect of TIVA and isoflurane on the activity of liver enzymes in patients undergoing laparoscopic cholecystectomy

Purpose
Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria:
Has no history of anesthesia in the past 6 months The patient's age is between 18 and 70 years old According to the ASA class, there will be one or two classes of anesthesia
Exclusion criteria:
The patient needs more medication during surgery Bleeding during surgery Laparoscopic change to laparotomy

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients' entry into this study will be a non-random sampling of "available" type. Then they will be divided into intervention and control groups randomly. The random number table will be used for the random specialization of the samples.

Blinding (investigator's opinion)
Double blinded

Blinding description
The research will be a non-random sampling of the type "available" and then divided into two intervention groups as randomized block allocation using the web system.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of North Khorasan of University of Medical Sciences
Street address
Shahriar Street - Research Assistant
City
Bojnurd
Province
North Khorasan
Postal code
74877-94149
Approval date
2016-09-19, 1395/06/29
Ethics committee reference number
985/95/پ

Health conditions studied

1

Description of health condition studied
Laparoscopic Cholecystectomy Surgery
ICD-10 code
K81
ICD-10 code description
Cholecystitis

Primary outcomes

1

Description
Anesthesia by Tiva
Timepoint
Time to start anesthesia
Method of measurement
Mg / kg body weight

2

Description
Isoflurane Anesthesia
Timepoint
Anesthesia maintenance time
Method of measurement
Mac Anesthetic Evaporator

3

Description
ALT Liver Enzyme
Timepoint
Hepatic enzyme activity preoperatively and postoperatively and 24 and 48 hours postoperatively
Method of measurement
Biochemical Autoanalysis Device

4

Description

AST Liver Enzyme
Timepoint
Hepatic enzyme activity preoperatively and postoperatively and 24 and 48 hours postoperatively
Method of measurement
Biochemical Autoanalysis Device

5

Description
ALP Liver Enzyme
Timepoint
Hepatic enzyme activity preoperatively and postoperatively and 24 and 48 hours postoperatively
Method of measurement
Biochemical Autoanalysis Device

Secondary outcomes

empty

Intervention groups

1

Description
After the patient enters the operating room, the supine position extends over the operating room bed and is monitored initially. An oximeter probe and pressure gauge cuff are attached to the patient's hand and a ringer serum is provided to the patient. Midazolam (2 mg) and fentanyl (100 mcg) were administered in all patients. Atracurium (0.5 mg / kg) and propofol (2 mg / kg) are used to induce anesthesia. After 3 minutes of hyperventilating the patient and performing the intubation, isoflurane inhaler anesthetic of 1.2 mc is used to maintain anesthesia in the first group.

Category
Treatment - Drugs

2

Description
After the patient enters the operating room, the supine position extends over the operating room bed and is monitored initially. An oximeter probe and pressure gauge cuff are attached to the patient's hand and a ringer serum is provided to the patient. Midazolam (2 mg) and fentanyl (100 mcg) were administered in all patients. Atracurium (0.5 mg / kg) and propofol (2 mg / kg) are used to induce anesthesia. After 3 minutes hyperventilating the patient and performing the intubation, propofol intravenous anesthetic is administered in the anesthetic phase of 100 micrograms per kg body weight plus remifanil (0.1 micrograms per minute body weight).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Hospital of Bojnourd University of Medical Sciences
Full name of responsible person
Javad Shahinfar
Street address
Dolat Square - Headquarters of North Khorasan University of Medical Sciences
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m.dartomi@nkums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Seyed Kaveh Hojjat
Street address
Shahriar Street - Next to Imam Ali Hospital - Research Assistant
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k.hojjat@nkums.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

Mahdieh Dartomi

Position

Master of Medical Education, Anesthesiology
Department, School of Nursing, North Khorasan
University

Latest degree

Master

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Mahdieh Dartomi

Position

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

After the end of the study some data and information will be loaded.

When the data will become available and for how long

6 months after plan completion

To whom data/document is available

Universities and scientific institutes

Under which criteria data/document could be used

Citing the source

From where data/document is obtainable

Email to responsible and consent

What processes are involved for a request to access data/document

It will take up to two months for email to be answered.

Comments