

# 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  
**City**  
Bojnurd  
**Province**  
North Khorasan  
**Postal code**  
74877-94149  
**Phone**  
+98 58 3229 7095  
**Email**  
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  
**City**  
Bojnurd  
**Province**  
North Khorasan  
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**Phone**  
+98 58 3229 7095  
**Email**  
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

**Street address**

Shahriar Street - Bojnurd School of Nursing

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**Province**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Bojnourd University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

Master

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Bojnourd University of Medical Sciences

**Full name of responsible person**

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**Phone**

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**Email**

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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**