

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison effects and Complications of propofol and isoflurane anesthesia for open cholecystectomy

#### Protocol summary

##### Study aim

Comparison effects and Complications of propofol and isoflurane anesthesia for open cholecystectomy.

##### Design

A randomized, single blinded (patients are unaware of the kind of used anesthetic medication) clinical trial with parallel groups (first group: Isoflurane Second group: Propofol) design, consisted of 60 patients, enrollment between February 2021 and 2022. Randomization of samples to each group will be done by random permuted blocks. according to the sample size, which is 60 people, the number of 6 blocks will be determined. And there will be an equal number of cards from each group in each block, the order in blocks will be in a random permuted method. Therefore, by performing each block, 10 patients will be selected.

##### Settings and conduct

The current study is a single centered clinical trial that will occur at Imam Ali Hospital in Zahedan. Patients will be divided into two intervention groups according to the permissive block randomization method. In this study patients are randomly divided into intervention groups after signing informed consent unawaresly.

##### Participants/Inclusion and exclusion criteria

Participants: Patients who will undergo a cholecystectomy procedure Inclusion criteria: Age between 15 and 80 years old American Society of Anesthesiologists (ASA) Class I & II Exclusion criteria: History of allergic reaction to these medication Drug abuse Common Cold Heart and Renal diseases, Hypertension Taking tranquilizer medication Not signing informed consent to participate in the study 2 failed attempts for Intubation

##### Intervention groups

First Intervention group: Isoflurane group. Isoflurane 1.5% 1.5MAC inhalation in Anesthesia time. Second Intervention group, Propofol group: Intravenous propofol infusion 100 µg/Kg per min in anesthesia time

##### Main outcome variables

Blood Pressure! Heart Rate! Awakening time from anesthesia! Nausea & Vomiting! Hoarseness! Staying time in recovery room

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120817010617N6**

Registration date: **2021-01-13, 1399/10/24**

Registration timing: **prospective**

Last update: **2021-01-13, 1399/10/24**

Update count: **0**

##### Registration date

2021-01-13, 1399/10/24

##### Registrant information

##### Name

morteza Sedaghat Kia

##### Name of organization / entity

zaums

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 1244 9540

##### Email address

morimedico@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-20, 1399/11/01

##### Expected recruitment end date

2022-01-21, 1400/11/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison effects and Complications of propofol and isoflurane anesthesia for open cholecystectomy

**Public title**

Comparison effects and Complications of propofol and isoflurane anesthesia for open cholecystectomy

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age between 15 and 80 years old American Society of Anesthesiologists (ASA) Class I & II

**Exclusion criteria:**

History of allergic reaction to these medication Drug abuse Common Cold Heart and Renal diseases, Hypertension Taking tranquilizer medication Not signing informed consent to participate in the study Two failed attempts for Intubation

**Age**

From **15 years** old to **80 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization of samples to each group will be done by random permuted blocks. according to the sample size, which is 60 people, the number of 6 blocks will be determined. And there will be an equal number of cards from each group in each block, the order in blocks will be in a random permuted method. Therefore, by performing each block, 10 patients will be selected(5 from each group).

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The patients are not aware of the kind of used anesthetic medication

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Zahedan University of Medical Sciences

**Street address**

Zahedan University of Medical Sciences, Dr.Hesabi Square

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743463

**Approval date**

2018-07-29, 1397/05/07

**Ethics committee reference number**

IR.ZAUMS.REC.1397.230

**Health conditions studied****1****Description of health condition studied**

Gallstone disease

**ICD-10 code**

K82.9

**ICD-10 code description**

Disease of gallbladder, unspecified

**Primary outcomes****1****Description**

Blood Pressure

**Timepoint**

Every 5 Minutes from beginning of intervention till the end of surgery

**Method of measurement**

Manometer

**2****Description**

Heart Rate

**Timepoint**

Every 5 Minutes from beginning of intervention till the end of surgery

**Method of measurement**

ECG Monitor

**3****Description**

Awakening time from anesthesia

**Timepoint**

When patient awakes and obeys

**Method of measurement**

Clinical Observation (Minutes)

#### 4

##### **Description**

Nausea & Vomiting

##### **Timepoint**

After patients awakening In recovery room

##### **Method of measurement**

Observe and record in a data form

#### 5

##### **Description**

Hoarseness

##### **Timepoint**

After patients awakening In recovery room

##### **Method of measurement**

Observe and record in a data form

#### 6

##### **Description**

Staying time in recovery room

##### **Timepoint**

After patients awakening In recovery room

##### **Method of measurement**

clinical, record in a data form

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

##### **Description**

First Intervention group, Isofluran group: Isofluran 1.5% 1.5MAC inhalation in Anesthesia time.

##### **Category**

Treatment - Drugs

#### 2

##### **Description**

Second Intervention group, Propofol group: Intravenous propofol infusion 100 µg/Kg per minutes in anesthesia time

##### **Category**

Treatment - Drugs

### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Ali-ebn Abi Taleb Hospital, Zahedan

###### **Full name of responsible person**

Nader Toofani Shahraki

###### **Street address**

Operation room, Zahedan Ali-ebn Abi Talib Hospital,

Salamat boulevard, Dr.Hesabi square

###### **City**

Zahedan

###### **Province**

Sistan-va-Balouchestan

###### **Postal code**

9816743111

###### **Phone**

+98 54 3329 5570

###### **Email**

ntuofanishahraki@gmail.com

### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Zahedan University of Medical Sciences

###### **Full name of responsible person**

Dr. Nour Mohammad Bakhshani

###### **Street address**

Dr Hesabi square

###### **City**

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###### **Postal code**

9816743463

###### **Phone**

+98 54 3329 5744

###### **Email**

zaums.research@gmail.com

##### **Grant name**

##### **Grant code / Reference number**

##### **Is the source of funding the same sponsor organization/entity?**

Yes

##### **Title of funding source**

Zahedan 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**

Zahedan University of Medical Sciences

###### **Full name of responsible person**

Nader Toofani Shahraki

###### **Position**

Anesthesia Resident

###### **Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Ali-ebn Abi Talib Hospital, Salamat Blvd, Dr.Hesabi Sq.

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Dr mehdi Heydari

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Nader Toofani Shahraki

**Position**

Anesthesia resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Operation room, Zahedan Ali-ebn Abi Talib Hospital, Salamat boulevard, Dr.Hesabi square

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**Province**

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**Email**

ntuofanishahraki@gmail.com

**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