

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

Zahedan

Province

Sistan-va-Balouchestan

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.

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 54 3329 5570

Email

ntuofanishahraki@gmail.com

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

Street address

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

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 54 3329 5570

Email

ntuofanishahraki@gmail.com

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

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 915 348 1606

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