

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jul 2026

### Comparison of propofol and sevoflurane with and without remifentanil on anesthesia depth and hemodynamic stability

#### Protocol summary

##### Study aim

Comparison of propofol and sevoflurane with and without remifentanil on anesthesia depth and hemodynamic stability

##### Design

four parallel groups ,randomised ,two tail blinded with 100 patients

##### Settings and conduct

In this study 100 patients who are going to have a laparoscopic cholecystectomy would be included.patients with age if 15 to 65,without history of addiction and with BMI less than 30 would enter the study. The anesthesiologist who manages anesthesia would perform anesthesia on the clinical situation of patient and without any information about bis values. Bis value and MAP and HR would be recorded every 5 minutes. The time between drug cessation and opening eyes of patient and severity of patient' pain also would be recorded. As mentioned before,the anesthesiologist who manages anesthesia do not have any information about bid values and manages anesthesia according to patients clinical situation.

##### Participants/Inclusion and exclusion criteria

age between 15 and 65 BMI less than 30 without history of addiction

##### Intervention groups

propofol propofol and remifentanil sevofluran sevofluran and remifentanil

##### Main outcome variables

1-Mean bis values indicating anesthesia deepness when sevofluran with or without remifentanil is used in comparrison with propofol. 2-Mean arterial pressure and heart rate change when sevofluran or propofol is used with or without remifentanil.

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20210309050653N1**

Registration date: **2022-05-25, 1401/03/04**

Registration timing: **retrospective**

Last update: **2022-05-25, 1401/03/04**

Update count: **0**

##### Registration date

2022-05-25, 1401/03/04

#### Registrant information

##### Name

elyas naghib

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4483 5090

##### Email address

naghib.e@skums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2021-11-22, 1400/09/01

#### Expected recruitment end date

2022-05-20, 1401/02/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of propofol and sevoflurane with and without remifentanil on anesthesia depth and hemodynamic stability

**Public title**

Comparison of propofol and sevoflurane with and without remifentanyl on anesthesia depth and hemodynamic stability

**Purpose**

Treatment

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

all patients with age of 15 to 65 years old GCS of 15

**Exclusion criteria:**

history of addiction BMI more than 30

**Age**

From **15 years** old to **65 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

selection of samples will be with available sampling and attribution of patients to the groups will be done with random allocation software. 80 patients who are going to have cholecystectomy surgery according to main and inclusion criteria will be considered. patients will be classified to four group with random allocation software. And it would be clarified that number one or number ten patient should be in which one of these groups and which drug they should receive.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

patients are not aware of type of anesthesia drugs and the anesthesiologist who manages anesthesia is not aware of BIS values and he manages depth of anesthesia according to his clinical experience

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics committee of Shahrekord University of Medical Sciences

**Street address**

ayatollah kaashani hospital, parastar street, hafez bulvard

**City**

shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8816758915

**Approval date**

2021-10-26, 1400/08/04

**Ethics committee reference number**

IR.SKUMS.REC.1400.171

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

anesthesia drugs

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

bispectral index value

**Timepoint**

5 min

**Method of measurement**

BIS device

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: patients who receive sevoflurane as a maintenance anesthetic drug. In this group, patients will receive sevoflurane with the dose of almost 3 MAC. The anesthesiologist may change the dose of sevoflurane according to the patient's medical condition without knowing the BIS value. The Danmeter DK-5000 device will be used for recording of BIS values.

**Category**

Treatment - Drugs

**2****Description**

Intervention group: patients who receive sevoflurane as a maintenance anesthetic drug. In this group, patients will receive sevoflurane with the dose of almost 3 MAC and remifentanyl with the dose of 0.2 microgram/kg/min. The anesthesiologist may change the dose of sevoflurane and remifentanyl according to the patient's medical condition without knowing the BIS value. The Danmeter DK-5000

device will be used for recording of BIS values.

**Category**

Treatment - Drugs

**3****Description**

Intervention group: patients who receive propofol as a maintenance anesthetic drug. In this group, patients will receive propofol with the dose of 150 microgram/kg/min. The anesthesiologist may change the dose of propofol according to the patient's medical condition without knowing the BIS value. The Danmeter DK-5000 device will be used for recording of BIS values.

**Category**

Treatment - Drugs

**4****Description**

Intervention group: patients who receive propofol and remifentanyl as a maintenance anesthetic drug. In this group, patients will receive propofol with the dose of 150 microgram/kg/min and remifentanyl with the dose of 0.2 microgram/kg/min. The anesthesiologist may change the dose of propofol and remifentanyl according to the patient's medical condition without knowing the BIS value. The Danmeter DK-5000 device will be used for recording of BIS values.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ayatollah Kashani hospital

**Full name of responsible person**

Elyas Naghib

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Massumeh Moezzi

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

Yes

**Title of funding source**

Shahre-kord 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**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Elyas Naghib

**Position**

resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Person responsible for scientific inquiries****Contact**

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Hossein Madineh  
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assistant professor  
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## Person responsible for updating data

### Contact

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Shahre-kord University of Medical Sciences  
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Elyas Naghib  
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**Latest degree**  
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**Other areas of specialty/work**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

No - There is not 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

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is 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

some parts of data could be shared.

### When the data will become available and for how long

since 1402

### To whom data/document is available

university researchers

### Under which criteria data/document could be used

similar research subject

### From where data/document is obtainable

Elyas Naghib

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

request should be with university email

### Comments