

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the prophylactic use of Ondansetron - Meperidine and Midazolam on shivering after laparoscopic cholecystectomy under general anesthesia

#### Protocol summary

##### Study aim

Determination and comparison between prophylactic use of ondansetron - meperidine and midazolam on shivering after laparoscopic cholecystectomy.

##### Design

Triple blind randomized clinical trial with control group -160 patients -defined with random allocation software to 4 groups.Patient do not know his group.Data collector do not know too.Also data analyzer.(double blind)

##### Settings and conduct

According to usefulness of these drugs in reducing of shivering after surgery and not being comparison between them in this research we compare use of them in reducing shiver after surgery in Alzahra Hospital in Isfahan.After sleeping on surgical bed and monitoring anesthesia will be inducted.After tracheal intubation anesthesia continues.30 mins to the end of surgery in A-B-C-D group respectively use midazolam - ondansetron - petedine with mentioned doses and the last group as control group. Shivering will be graded in recovery.Patient do not know his group.Data collector and also data analyzer do not know too.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: people between 20 to 70 years old - patient satisfaction -ASA 1-2 Exclusion criteria : infectious disease - neuromascular disease - addiction - heart failure - chronic mental disease that needs drug - use of alpha and beta blocker - temperature above 38 and below 36.5

##### Intervention groups

All three drugs will be administered 30 minutes to the end of surgery. In the first group 75 microgram/kg of midazolam will be used.In some researches midazolam cure shivering after surgery.In the second administer 8 mg ondansetron.It is usefull in reducing post operative shivering ,too.Second group use 0.5 mg/kg petedine .Use of this drug in different doses are useful in prevention

and cure of post operative shivering.Last group as control group and comparison with others do not give any drug.

##### Main outcome variables

Shivering

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100926004819N5**

Registration date: **2022-01-16, 1400/10/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-01-16, 1400/10/26**

Update count: **0**

##### Registration date

2022-01-16, 1400/10/26

##### Registrant information

##### Name

Saied Morteza Heidari Tabaei Zavareh

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1267 6415

##### Email address

m\_heidari@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-15, 1400/10/25

##### Expected recruitment end date

2022-03-10, 1400/12/19  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty  
**Scientific title**  
Comparison of the prophylactic use of Ondansetron - Meperidine and Midazolam on shivering after laparoscopic cholecystectomy under general anesthesia  
**Public title**  
Comparison between Ondansetron - Meperidine and Midazolam on postoperative shivering  
**Purpose**  
Prevention  
**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patient candidate for laparoscopic cholecystectomy  
Patient satisfaction for participation ASA1/2  
**Exclusion criteria:**  
Infectious disease Neuromuscular disease Drug addiction Hurt failure (EF<40%) Chronic mental illness that needs drug Use of alpha and beta blocker Temperature above 38 and below 36.5  
**Age**  
From **20 years** old to **70 years** old  
**Gender**  
Both  
**Phase**  
N/A  
**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**  
Target sample size: **160**  
**Randomization (investigator's opinion)**  
Randomized  
**Randomization description**  
Randomization is done with simple randomization. Also randomization unit is individual. We do not use stratified randomization. Randomization tool is SPSS software.  
**Blinding (investigator's opinion)**  
Double blinded  
**Blinding description**  
Patient do not know his group. The person who collect data don,t know it. The person who analyze statistics don,t know too.  
**Placebo**  
Used  
**Assignment**  
Parallel  
**Other design features**  
**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Isfahan University Of Medical Sciences

##### Street address

Ethics committee of Isfahan University of Medical Sciences;Hezarjarib Ave

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2021-07-16, 1400/04/25

#### Ethics committee reference number

IR.MUI.MED.REC.1400.318

## Health conditions studied

### 1

#### Description of health condition studied

shivering after laparoscopic cholecystectomy

#### ICD-10 code

T88.5

#### ICD-10 code description

Other complications of anesthesia

## Primary outcomes

### 1

#### Description

shivering under crossley classification

#### Timepoint

after 15-30-45-60 minute in recovery

#### Method of measurement

crossley classification

### 2

#### Description

intensity of pain after surgery

#### Timepoint

after 15-30-45-60 minute in recovery

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: For comparison with patients who give petedine - midazolam or ondansetron with mentioned doses as single dose 30 mins to the end of laparoscopic cholecystectomy and as control group in this level they do not give any drug. Other processes in this group are the same as other groups.

**Category**

Prevention

**2****Description**

Intervention group: They give 75 microgram/kg midazolam 30 mins to the end of laparoscopic cholecystectomy as single dose. Midazolam 5,15 (midazolam ampule 5,15 mg/ml) made in Exir pharmacy as intravenous injection.

**Category**

Prevention

**3****Description**

Intervention group: 30 mins to the end of laparoscopic cholecystectomy 8 mg Ondansetron as single intravenous dose. Exir Ondansetron 8 will be used. Ondansetron ampule as 2 mg/ml (2,4 ml) is in the market.

**Category**

Prevention

**4****Description**

Intervention group: 30 mins to the end of laparoscopic cholecystectomy Petedine 0.5 mg/kg as single intravenous dose. Petedine 50, 100 ampules are made in Exir company that are 50, 100 mg/ml (1, 2 ml).

**Category**

Prevention

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

Alzahra hospital

**Full name of responsible person**

Navid Mirsatari

**Street address**

Sofeh Blvd

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3668 5555

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m\_heidari@med.mui.ac.ir

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

Esfahan University of Medical Sciences

**Full name of responsible person**

دکتر مژگان مرتضوی

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No 4 Building ; Isfahan medical sciences university ;  
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**Email**

research@mui.ac.ir

**Web page address**

<https://research.mui.ac.ir>

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

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Saied Morteza Heidari Tabaei Zavareh

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Saied Morteza Heidari Tabaei Zavareh  
**Position**  
Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
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## Person responsible for updating data

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Esfahan University of Medical Sciences  
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**Position**  
Professor  
**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

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is 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

Yes - There is a plan to make this available

### Title and more details about the data/document

Research data will be shared after patients become unrecognizable

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

reachable after 2022

### To whom data/document is available

Researchers in the universities and scientific centers

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

medical sciences researchers for clinical use or more researches

### From where data/document is obtainable

Hezarjarib Ave -Isfahan Medical University or Email:  
m\_heidari@med.mui.ac.ir

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

Isfahan Medical University library or Email address

### Comments