

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Comparing the effect of Pethidine, Ketamin and Ondansetron to prevent postoperative shivering in elective cholecystectomy under general anesthesia

#### Protocol summary

##### Summary

The aim of this study is finding a proper alternative for Pethidine to prevent postoperative shivering. Inclusion criteria are having Laparoscopic cholecystectomy surgery and age between 20-50 years old. Exclusion criteria are smoking, addiction, cardiovascular disease, age less than 20 and age more than 50. In this randomized triple-blind clinical trial, 160 patients aged from 20-50 years with ASA class I & II undergoing elective cholecystectomy are randomly divided into four equal groups. Anesthesia procedure is similar in all groups. 15 minutes before the end of surgery, 0.4mg/kg pethidine, 0.25mg/kg ketamin, 0.1mg/kg ondansetron and normal saline, is injected randomly to the groups. Hemodynamic changes (systolic blood pressure, diastolic blood pressure, and heart rate), body temperature (before injection, 5 minutes after injection, and after stability), and nausea & vomiting after surgery are measured and compared between groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016032326340N1**

Registration date: **2016-03-23, 1395/01/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-03-23, 1395/01/04

##### Registrant information

###### Name

Nasim Zarrin

###### Name of organization / entity

Qazvin University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 3334 2024

###### Email address

n.zarin@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Qazvin University of Medical Sciences

##### Expected recruitment start date

2015-01-20, 1393/10/30

##### Expected recruitment end date

2015-12-21, 1394/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of Pethidine, Ketamin and Ondansetron to prevent postoperative shivering in elective cholecystectomy under general anesthesia

##### Public title

Comparing the effect of Pethidine, Ketamin and Ondansetron to prevent postoperative shivering in elective removal of gallbladder under general anesthesia

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: Having Laparoscopic cholecystectomy surgery; age between 20-50 Exclusion criteria: Smoking; addiction; cardiovascular disease; age less than 20; age more than 50

**Age**

From **20 years** old to **50 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **160**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Triple blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

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

empty

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

Qazvin University of Medical Sciences

**Street address**

Qazvin, Shahid Bahonar Boulvar

**City**

Qazvin

**Postal code**

3419915315

**Approval date**

2015-01-10, 1393/10/20

**Ethics committee reference number**

20/9884/3

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

Prevention of postoperative shivering

**ICD-10 code**

T88.9

**ICD-10 code description**

Complication of surgical and medical care, unspecified

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

Diastolic Blood Pressure

**Timepoint**

before injection, 5 minutes after injection, after stability in recovery

**Method of measurement**

check list

**2****Description**

Heart Rate

**Timepoint**

before injection, 5 minutes after injection, after stability in recovery

**Method of measurement**

check list

**3****Description**

Body Temperature

**Timepoint**

before injection, 5 minutes after injection, after stability in recovery

**Method of measurement**

check list

**4****Description**

nausea and vomiting

**Timepoint**

postoperative

**Method of measurement**

check list

**5****Description**

shivering

**Timepoint**

postoperative

**Method of measurement**

check list

**6****Description**

systolic blood pressure

**Timepoint**

before injection, 5 minutes after injection, after stability in recovery

**Method of measurement**

check list

**Secondary outcomes**

empty

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

Group A; Received Pethidine 0.4 mg/ kg  
**Category**  
Treatment - Drugs

2

**Description**  
Group B; Received Ketamin 0.25 mg/kg  
**Category**  
Treatment - Drugs

3

**Description**  
Group C; Received Ondansetron 0.1 mg/kg  
**Category**  
Treatment - Drugs

4

**Description**  
Group D; Received Normal Saline 2 cc  
**Category**  
Treatment - Drugs

## Recruitment centers

1

**Recruitment center**  
**Name of recruitment center**  
Velayat Hospital of Qazvin  
**Full name of responsible person**  
Dr Nasim Zarrin  
**Street address**  
Qazvin, Minoodar, across from Elahiye Restaurant  
**City**  
Qazvin

## Sponsors / Funding sources

1

**Sponsor**  
**Name of organization / entity**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Dr Marzie Beighom Khezri  
**Street address**  
Shahid Bahonar Boulvar ,Qazvin  
**City**  
Qazvin  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Qazvin University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**

*empty*  
**Domestic or foreign origin**  
*empty*  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

**Contact**  
**Name of organization / entity**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Dr Nasim Zarrin  
**Position**  
Anesthesia Assistant  
**Other areas of specialty/work**  
**Street address**  
No 42, MehrdadAalley, Padegan Street, Qazvin  
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**Postal code**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Anesthesia Assistant

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*