Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

Summary

The aim of this study is finding a proper alternative for Pethidine to prevent postoperative shivering.Inclision criteria are having Laparoscopic cholecyctectomy 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 cholecyctectomy 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 betweeen 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

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Iran (Islamic Republic of)

Phone

+98 28 3334 2024

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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 cholecyctectomy 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

Inclision criteria: Having Laparoscopic cholecyctectomy 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/د

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

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Full name of responsible person

Dr Nasim Zarrin

Position

Anesthesia Assistant

Other areas of specialty/work

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Full name of responsible person

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Web page address

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