

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Clinical trial comparing the effects of ketorolac and pethidine on the postoperative shivering in patients undergoing cholecystectomy

Protocol summary

Summary

This study was designed to evaluate the effect of administration of intravenous (IV) ketorolac in comparison with Pethidine on shivering, during the first minutes following surgery in the recovery period. This study was a randomized, double blind clinical trial in the third phase and single center. Sixty patients with American Society of Anesthesiologists physical status I and II, in the age range of 20 to 60 years who were scheduled for cholecystectomy under general anesthesia, were randomly assigned to two groups. Patients with hepatic and renal insufficiency, gastrointestinal bleeding, a need for blood transfusion during surgery, a history of allergy to non-steroidal anti-inflammatory drugs (NSAIDs) were excluded. When patients arrived to the operation room, they were randomly assigned to one of two equally divided groups (30 patients each) by using the closed envelop technique. Group K received ketorolac (a non-selective COX inhibitor) 30 mg IV and group P received Pethidine (meperidine) 0.5 mg/kg IV, 20–30 minutes before completion of surgery. The incidence and grades of postoperative shivering and pain intensity score were recorded during the recovery period. Postoperative shivering grades were evaluated 3 times in minutes 0, 5, 15. Other postoperative complications were asked in the questionnaire.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016080229162N1**

Registration date: **2016-09-09, 1395/06/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-09, 1395/06/19

Registrant information

Name

Neda Fathi

Name of organization / entity

Ardabil University of Medical Science

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ne.fathi@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ardabil University of Medical Sciences

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-08-21, 1395/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparing the effects of ketorolac and pethidine on the postoperative shivering in patients undergoing cholecystectomy

Public title

Effect of Ketorolac in incidence of post operative shivering

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : abdominal surgeries (cholecystectomy); in the age range 20_60 years; American Society of Anesthesiologists (ASA) physical status I-II. Exclusion criteria : Patients with cardiac, pulmonary, hepatic, renal, thyroid, or neuromuscular disease; those who took chronic drug or abused alcohol; operations that lasts more than 120 min; gastrointestinal bleeding; need for blood transfusion during surgery; a history of allergy to non steroidal anti-inflammatory drugs (NSAIDs) or other agents to be use; inability to cooperate.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Double-blind, randomized study was done by using sealed envelopes technique.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

Street address

Ardabil Complex Univesity, Daneshgah st., Ardabil

City

Ardabil

Postal code

56189-85991

Approval date

2015-12-19, 1394/09/28

Ethics committee reference number

IR. ARUMS.REC.1394.68

Health conditions studied

1

Description of health condition studied

cholecystectomy undergoing general anesthesia

ICD-10 code

K80, K81,

ICD-10 code description

Cholelithiasis, Cholecystitis, Other diseases of biliary tract

Primary outcomes

1

Description

check in scale of shivering

Timepoint

after operation in recovery ward on entrance and 5 and 15 minutes later

Method of measurement

score

Secondary outcomes

empty

Intervention groups

1

Description

Group intervention : 30mg ketorolac intravenously (IV)

Category

Treatment - Drugs

2

Description

Group control : 0.5mg/kg Pethidine (meperidine) intravenously (IV)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemi Hospital

Full name of responsible person

-

Street address

Fatemi hospital, Imam Khomeini st., Ardabil

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Ardabil University of
Medical Sciences

Full name of responsible person

Dr. Akbar Pirzadeh

Street address

Medical and Paramedical Faculty, Ardabil University of
Medical Sciences, Daneshgah st., Ardabil

City

Ardabil

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of Ardabil 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**

Ardabil University of Medical Sciences

Full name of responsible person

Neda Fathi

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Medical student

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Dr. Ghodrat Akhavan Akbari

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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

