

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 45 3374 7222

###### Email address

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

**Position**

Medical student

**Other areas of specialty/work****Street address**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ardabil University of Medical Sciences

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Dr. Ghodrat Akhavan Akbari

**Position**

Anesthesiologist

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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*

