

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Comparison of the efficiency and side effects of morphine and diclofenac suppositories with intramuscular pethidine in controlling post operative pain in appendectomy and inguinal hernia

#### Protocol summary

##### Summary

In this study, the efficacy and complications of two suppositories including morphine and diclofenac were assessed versus pethidine as a safe method for post operative analgesia in appendectomy&surgery of inguinal hernia. The study population included patients diagnosed with acute appendicitis and Inguinal Hernia undergoing surgery at the Fatemi Hospital (and in the age group ranged from 18-70). Pregnant patients and patients with neurological or psychiatric disorders and other systemic diseases were not included in the study. The sample size of 75 people who were randomly assigned into 3 groups of 25 patients were studied in double blind form. The first group received 10 mg of suppository morphine during the 2th, 6th, 12th and 24th hours after surgery, and the second group received suppository diclofenac during the same times. In the third group, if the patient had postoperative pain, 50 mg intramusclar pethidine (PRN) was used to control pain provided that the patient had a score above 4. To measure patient pain score based on VAS criteria , graded ruler of 0 to 10 (according to the variables table) was used, To measure patient vomiting& nausea score N&V scales was Used, to score the patients sedation ramsy sedation score was used. And were enclosed in the forms prepared for this aim.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017071134841N2**

Registration date: **2017-09-02, 1396/06/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-09-02, 1396/06/11

##### Registrant information

###### Name

Ahmad Ghazi

###### Name of organization / entity

Ardabil University Of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 45 3324 8888

###### Email address

a.gazi@arums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Deputy Research Ardabil University of Medical Sciences

##### Expected recruitment start date

2013-03-27, 1392/01/07

##### Expected recruitment end date

2014-03-20, 1392/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the efficiency and side effects of morphine and diclofenac suppositories with intramuscular pethidine in controlling post operative pain in appendectomy and inguinal hernia

##### Public title

Comparison of the efficiency and side effects of morphine and diclofenac suppositories with

intramuscular pethedine in controlling post operative pain in appendectomy and inguinal hernia

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Patients underwent appendectomy and inguinal hernia in the age group of 18-70 years. Pregnant women, patients with neurological disease or psychiatric disorders, with history of seizure, with acute or chronic kidney disease, history of gastrointestinal ulcer, drug users Psychotropic substances users or alcohol consumption and those with hemorrhoids or anus disorder were not included in the study.

### **Age**

From **18 years** old to **70 years** old

### **Gender**

Both

### **Phase**

2

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **75**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

The Ethics Committee of Ardabil University of Medical Sciences

##### **Street address**

Ardabil Complex Univesity, Daneshgah st, Ardabil

##### **City**

ardabil

##### **Postal code**

5618985991

#### **Approval date**

2013-04-28, 1392/02/08

#### **Ethics committee reference number**

arums.rec.1392.7

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

postoperative pain control in appendectomy

#### **ICD-10 code**

k35, k36,

#### **ICD-10 code description**

Diseases of appendix

### **2**

#### **Description of health condition studied**

postoperative pain control in inguinal hernia

#### **ICD-10 code**

k40

#### **ICD-10 code description**

Inguinal hernia

## **Primary outcomes**

### **1**

#### **Description**

pain

#### **Timepoint**

In the hours 2,6,12,24 after surgery

#### **Method of measurement**

To measure the final outcome of the study patient pain score was based on the visual analogue score criteria with metric roler ranged from zero to ten according to the variables table

## **Secondary outcomes**

### **1**

#### **Description**

patients sedation score

#### **Timepoint**

during the 2 nd,6th,12th,24th hours after surgey

#### **Method of measurement**

to score the patients sedation ramsy sedation score was used

### **2**

#### **Description**

nausea and vomiting

#### **Timepoint**

during the 2 nd,6th,12th,24th hours after surgey

#### **Method of measurement**

The amont of N&V were measured according to N&V score

## **Intervention groups**

### **1**

#### **Description**

In the first group, suppository morphine 10 mg was administered at hours 2 nd, 6th, 12th and 24th after surgery.

**Category**

Treatment - Drugs

**2****Description**

In the second group, diclofenac suppository was given 100 mg at 2 nd, 6th, 12th, and 24th hours after surgery.

**Category**

Treatment - Drugs

**3****Description**

In the control group or the third group, if the patient had postoperative pain and the patient had a pain score above 4, 50 mg intramuscular pethidine was used to control pain.

**Category**

Treatment - Drugs

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

DR.Fatemi Hospital Ardabil

**Full name of responsible person**

DR.Ghodrat Akhavan Akbari

**Street address**

Ardabil Complex Univesity, Daneshgah st, Ardabil

**City**

Ardabil

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

Deputy Research of Ardabil University of Medical Sciences

**Full name of responsible person**

Dr.Shahram Habibzade

**Street address**

Ardabil Complex Univesity, Daneshgah st, Ardabil

**City**

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

Yes

**Title of funding source**

Deputy 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**

Shahram Galiche Chi

**Position**

Intern

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

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**Full name of responsible person**

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**Position**

Pain Fellowship

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**Position**

Anesthesiologist

**Other areas of specialty/work**

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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*