

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 intramuscular 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 Ramsay 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 alchohol 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

Ardabil

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**

Ardabil Complex Univesity, Daneshgah st, Ardabil

City

Ardabil

Postal code

5618985991

Phone

+98 45 3352 2247

Fax

+98 45 3352 2196

Email

Dr.AkhavanAkbari@Gmail.com;

Dr.GhaziAhmad@Gmail.com

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

Ardabil University of Medical Sciences

Full name of responsible person

Dr.Ghodrat Akhavan Akbari

Position

Pain Fellowship

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

Ardabil Complex Univesity, Daneshgah st, Ardabil

City

Ardabil

Postal code

5618985991

Phone

+98 45 3352 2247

Fax

+98 33522196

Email

Dr.AkhavanAkbari@Gmail.com;

Dr.GhaziAhmad@Gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Ardabil University of Medical Sciences
Full name of responsible person
Dr.Ahmad ghazi
Position
Anesthesiologist
Other areas of specialty/work
Street address
Ardabil Complex Univesity, Daneshgah st, Ardabi
City
Ardabil
Postal code
5618985991
Phone
+98 45 2223 2521
Fax
+98 45 3352 2196
Email
a.gazi@arums.ac.ir

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