Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effects of intravenous ibuprofen and pump pain with pump pain alone on postoperative pain in patients undergoing open appendectomy and inguinal hernia: a clinical trial

Protocol summary

Summary

This double-blind randomized clinical trial is conducted on patient who are candidate for open appendectomy or inguinal hernioplasty in Fatemi Hospital of Ardabil in 2016. In this study both patients and researchers will be blinded and medications will be put in two packets labeled 1 and 2 and each patient will be given one randomly. The medications will be injected by the research collaborator. 60 patients aged 20-60 years who are candidate for open appendectomy or inguinal hernioplasty are included in this study and exclusion criteria includes patients with underlying disease, gastrointestinal disease, opioid or NSAIDs' allergy or drug-addicted. Patients are randomly divided into two groups; first group receives 400 mg intravenous ibuprofen in the recovery and at 6, 12, and 18 hours after surgery in addition to 15 ug/ml fentanyl pump. Second group only receives 15 ug/ml fentanyl pump. Pain pump acts with a lockout time of 15 minutes with 1 ml bolus injection with 15ug/ml concentration. For pain management with this pump, 30 cc fentanyl diluted in 70 ml normal saline (15 ug/ml) and all patients can use the pump on pain onset. In the two study groups, VAS will be measured in hours 1, 6, 12, 18, and 24 and opioid consumption and nausea and vomiting will be compared in these groups

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608284131N3**
Registration date: **2016-09-17, 1395/06/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-09-17, 1395/06/27

Registrant information

Name

Afshan Sharghi

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 1551 2012

Email address

a.sharghi@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ardabil University of Medical Sciences

Expected recruitment start date

2016-09-20, 1395/06/30

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of intravenous ibuprofen and pump pain with pump pain alone on postoperative pain in patients undergoing open appendectomy and inguinal hernia: a clinical trial

Public title

Ibuprofen effect of postoperative pain management

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients aged 20-60 years; candidate for open appendectomy or inguinal hernioplasty surgery. Exclusion criteria: underlying disease; gastrointestinal disease; opioid allergy; NSAID allergy; drug addiction, refusal of patients to consent for participating in the study

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

The study will be performed as a randomized, double-blind, controlled clinical trial using closed envelope method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Ardabil University Of Medical Science

Street address

Daneshgah St، Ardabil

City

Ardabil

Postal code

Approval date

2016-05-04, 1395/02/15

Ethics committee reference number

IR.ARUMS.REC.1395.4

Health conditions studied

1

Description of health condition studied

Open appendectomy

ICD-10 code

K35.8, K36

ICD-10 code description

Acute appendicitis, other and unspecified, Other appendicitis

2

Description of health condition studied

inguinal hernia

ICD-10 code

K40.9

ICD-10 code description

Unilateral or unspecified inguinal hernia, without obstruction or gangrene

Primary outcomes

1

Description

Pain

Timepoint

1, 6, 12, 18, and 24 hours after surgery

Method of measurement

Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 400 mg ibuprofen intravenous injection in recovery which will be repeated on hours 1, 6, 12, 18 after surgery in addition to 15 ug/ml fentanyl pain pump

Category

Treatment - Drugs

2

Description

Control group: bolus 15 ug/ml fentanyl pain pump

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ardabil Fatemi Hospital

Full name of responsible person

Dr. AmirAhmad Arabzadeh

Street address

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
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
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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