

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison effect of the intraperitoneal injection of Marcaine with intravenous Ketorolac in postoperative pain control after Laparoscopic Cholecystectomy

Protocol summary

Summary

The main objective of this study is to compare the effect of the intraperitoneal injection of Marcaine with Intravenous Ketorolac on postoperative pain control after laparoscopic cholecystectomy surgery. Methods: A double blind randomized clinical trial was conducted in the Imam hospital for elective laparoscopic cholecystectomy. In this study the patients and researchers are blinded. Drugs put in three envelope for 1,2,3 and will receive for one patient. So that patient and researcher were blinded and partners of the project will injected. The inclusion criteria: Patients are with average 20-60 years old that needs elective laparoscopic cholecystectomy surgery. The exclusion criteria: Addicted patients, gastrointestinal diseases, susceptible diseases, sensitivity to anesthetic drugs and analgesics drugs postoperative pain. At first, Intravenous pain pump was applied to all three groups in recovery rooms. Pumps acts such as lock-out time for every 15 minutes, and (bolus) infusion pumps 0.1ml at a concentration of 15mg / ml. The density of pumps was 30cc Fentanyl in 70 mg of normal saline and patient can use the pumps when pain. Then the patients classified randomly in to three groups. Group A: the end of laparoscopic cholecystectomy injected 40 ml solution intraperitoneal Marcaine (0.25%). After intraperitoneal injection tilt the bed. Group B: injected Intravenous Ketorolac (30 cc) once 30 minute before the end of completion of the surgery and again re-injected Intravenous Ketorolac (30 cc) 8 and 16 hours after surgery Group C: injected 40 ml of intraperitoneal normal saline with (plus) 2 ml of intravenous normal saline such as group 1 and 2. The visual analogue scale (VAS) has been used in this study for measurement pain of patient at 2,8,16,24 hours after surgery and compare consumption Fentanyl and nausea and vomiting and scapula pain and abdominal pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201606064131N2**

Registration date: **2016-09-21, 1395/06/31**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-21, 1395/06/31

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

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Recruitment status

Recruitment complete

Funding source

Ardabil University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of the intraperitoneal injection of Marcaine with intravenous Ketorolac in postoperative pain control after Laparoscopic Cholecystectomy

Public title

Comparison effect of the intraperitoneal injection of Marcaine with intravenous Ketorolac in postoperative pain control

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria : Patients aged 20-60 years old : elective laparoscopic cholecystectomy surgery. The Exclusion criteria: Addicted patient :gastrointestinal diseases, susceptible diseases, sensitivity to anesthetic or analgesics drugs

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: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Ardabil University of Medical Sciences

Street address

Daneshgah st, Ardabil

City

Ardabil

Postal code

Approval date

2015-12-19, 1394/09/28

Ethics committee reference number

IR.ARUMS.REC.1394.70

Health conditions studied

1

Description of health condition studied

laparoscopic cholecystectomy

ICD-10 code

K80

ICD-10 code description

Cholelithiasis

Primary outcomes

1

Description

Pain

Timepoint

2 & 8 & 16 & 24 hours after surgery

Method of measurement

Visual Analog Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group : Intravenous ketorolac (30 cc) once before completion of the surgery and again re-injected 8 and 16 hours after surgery

Category

Treatment - Drugs

2

Description

Control group : Intraperitoneal injection of 40 ml of normal saline with (plus) 2 ml of intravenous injection of normal saline

Category

Placebo

3

Description

Intervention group : intraperitoneal injection of Marcaine (0.25%) in 40 ml normal saline.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemi Hospital Ardabil

Full name of responsible person

Dr Amir Ahmad Arabzadeh

Street address

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr Sharhram Habibzadeh

Street address

Daneshgah St, Ardabil University of Medical Sciences

City

Ardabil

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Dr Amir Ahmad Arabzadeh

Position

General Surgeon

Other areas of specialty/work

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Afshan Sharghi

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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