Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

Summary

The main objective of this study is to comparsion 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 pumps0.1ml 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 1and 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 vomting and scapula pain andabdominal 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
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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 o f Marcaine with intravenous Ketorolac in postoperative pain control after Laparoscopic Cholecystectomy

Public title
Comparison effect of the intraperitoneal injection o f 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 Anlalog 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 Śharhram Habibzadeh
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Daneshgah St, Ardabil University of Medical Sciences
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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
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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