Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the effect of Paracetamol and Morphine and Ketorolac with IV_PCA in control of post operative pain in open cholecystectomy

Protocol summary

Summary

The aim of this study was the comparison of the analgesic effect of Morphine and Paracetamol and Ketorolac with IV_PCA in 330 patients undergoing open cholecystectomy , were studied using double blind randomized clinical trial (110 patients in each groups) in the Shahid Rajaee Centre and Velayat Hospital.inclusion criteria include :ASA 1and 2 patients 20 _50 years who were undergoing open cholecystectomy operation takes less than 2.5 hours.Exclusion criteria include: People using opioids, painkillers and sedatives regularely and in large doses and patients with ahistory of lung or liver problems. The parameters of the severity of pain and nausea (VAS), hemodynamic changes (BP , HR), pruritus, O2 saturation and patient satisfaction (VAS) were measured by a trained colleague.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031717048N1**
Registration date: **2014-09-17, 1393/06/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-09-17, 1393/06/26

Registrant information

Name

Monadi Hamidfar

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Science

Expected recruitment start date

2013-09-14, 1392/06/23

Expected recruitment end date

2014-08-14, 1393/05/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Paracetamol and Morphine and Ketorolac with IV_PCA in control of post operative pain in open cholecystectomy

Public title

Comparison the effect of Morphine ,Paracetamol and Ketorolac with Patient Control Analgesia in post operative pain in open cholecystectomy surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Patient with ASA 1 and 2 ; 20 _50 years ; who werwe undergoing open cholecystectomy operation ; takes less than 2.5 hours . Exclusiom criteria : People using opioids , painkillers and sedatives regularely and in large doses.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **330**
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
Qazvin University Of Medical Sciences
Street address
shahid Bahonar bolivar , Qazvin
City
Qazvin
Postal code
Approval date
2013-09-04, 1392/06/13
Ethics committee reference number
7783/20/28

Health conditions studied

1

Description of health condition studied
Pain control
ICD-10 code
R10.1
ICD-10 code description
Pain localized to upper abdomen

Primary outcomes

1

Description
Post Operative Pain
Timepoint
2, 4, 6 and 8 hours after intervention
Method of measurement
VAS

Secondary outcomes

1

Description
Nausea
Timepoint
2 , 4 , 6 and 8 hours after intervention
Method of measurement
VAS

2

Description
satisfaction
Timepoint
2, 4, 6 and 8 hours after intervention
Method of measurement
VAS

3

Description
Pruritus
Timepoint
2, 4, 6 and 8 hours after intervention
Method of measurement
yes or no

4

Description
Arterial Oxygen Desaturation
Timepoint
2, 4, 6 and 8 hours after intervention
Method of measurement
Yes or no

5

Description
Changes in blood pressure
Timepoint
2, 4, 6 and 8 hours after intervention
Method of measurement
In to three groups: Low, medium and high

6

Description
changes in heart rate
Timepoint
2, 4, 6 and 8 hours after intervention
Method of measurement
in to three groups : low , medium and high

Intervention groups

1

Description
Morphine, controlling pain after laparatomy surgery (cholecystectomy). with maximum dose 0.02 mg per kg

in hour with intravenous PCA. lasting 8 hour after surgery.

Category

Treatment - Drugs

2

Description

Paracetamol. controlling painafter laparotomy surgery (cholecystectomy). with maximum dose 1 mg per kg per hour with intravenous PCA. lasting 8 hours after surgery.

Category

Treatment - Drugs

3

Description

Ketorolac controlling pain after laparatomy surgery (cholecystectomy).with maximum dose1 mg per kg withintravenous PCA.lasting 8 hours after surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaii Hospital

Full name of responsible person

Monadi Hamidfar

Street address

Padegan avenue , Qazvin

City

Qazvin

2

Recruitment center

Name of recruitment center

Velayat Hospital

Full name of responsible person

Monadi Hamidfar

Street address

Taavon square , 22 Bahman bolivar, Elahie , Qazvin

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Qazvin University of Medical Sciences

Street address

Bahonar Bolivar , Qazvin

City

Qazvin

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

Qavin University of Medical sciences

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Position

Resident of anesthesiology

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