

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 Rajaei 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 regularly 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

Qazvin University medical science

Country

Iran (Islamic Republic of)

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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 . Exclusion criteria : People using opioids , painkillers and sedatives regularly 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 laparotomy 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 pain after 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 laparotomy surgery (cholecystectomy). with maximum dose 1 mg per kg with intravenous 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

Qazvin University of Medical sciences

Full name of responsible person

Dr Monadi Hamidfar

Position

Resident of anesthesiology

Other areas of specialty/work

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Full name of responsible person

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Position

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

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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