Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of oral Oxycodone versus intravenous Ketorolac on post laparoscopic cholecystectomy pain

Protocol summary

Study aim
Comparison of the effect of oral Oxycodone versus intravenous Ketorolac on post laparoscopic cholecystectomy pain

Design
Double blinded randomized clinical trial

Settings and conduct
60 patients referred to Loghman Hospital operating room will be divided into 2 groups: receiving oxycodone or ketorolac. Before induction of anesthesia the former group receive 30 mg of oral oxycodone, while 30 mg ketorolac in 100cc normal saline is administered to the latter intravenously over 30 minutes.Postoperative pain scores are measured and documented based on NRS.

Participants/Inclusion and exclusion criteria
Inclusion Criteria Patients candidate for elective laparoscopic cholecystectomy Age between 18-65 year No history of drug abuse No history of psychologic disease No history of sensitivity to drugs in study Exclusion Criteria

Intervention groups
Oxycodone group: In addition to routine analgesics, patients receive oral oxycodone to the control postoperative pain. Ketorolac group: In addition to routine analgesics, patients receive intravenous ketorolac to the control postoperative pain.

Main outcome variables
Severity of postoperative pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181216041991N1**
Registration date: **2019-01-23, 1397/11/03**
Registration timing: **registered_while_recruiting**
Last update: **2019-01-23, 1397/11/03**
Update count: **0**

Registration date
2019-01-23, 1397/11/03

Registrant information
Name
masoud nashibi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 5542 4040
Email address
masoudnashibi@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-10, 1397/10/20

Expected recruitment end date
2019-02-19, 1397/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of oral Oxycodone versus intravenous Ketorolac on post laparoscopic cholecystectomy pain

Public title
Comparison of the effect of oral Oxycodone versus intravenous Ketorolac on post laparoscopic cholecystectomy pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients candidate for laparoscopic cholecystectomy Age between 18-65 year

Exclusion criteria:

No history of drug abuse No history of psychologic disease No allergy to studied drugs No pregnancy and lactation No clinical sign due to sepsis or other inflammatory disease No history of liver and renal failure No history of GI bleeding No history of coagulopathies No history of sign of neuropathy No diagnosis of gangrenous cholecystitis No diagnosis of generalized peritonitis

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Sealed envelop method

Blinding (investigator's opinion)

Double blinded

Blinding description

Researcher open the pockets confidentially to learn the patient's group. The patients pain scores and other results are documented by an unaware personnel.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2019-01-06, 1397/10/16

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.837

Health conditions studied

1

Description of health condition studied

The effect of medications on post laparoscopic cholecystectomy pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Postoperative pain

Timepoint

1,2,4,6,12 hours postoperative

Method of measurement

Numerical rating Scale;The NRS is a 10 cm horizontal bar which is divided to 0-10 pieces. Respondent selects a whole number (0–10 integers) that best reflects the intensity of his/her pain. Number zero eqauals no pain, while number ten means unbearable pain.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the first group patients receive 30 mg of oral oxycodone before anesthesia induction.

Category

Treatment - Drugs

2

Description

Intervention group: In the second group before anesthesia induction patients receive 30 mg of intravenous ketorolac dissolved in 100 ml normal saline in 30 minute.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

loghman hakim hospital

Full name of responsible person
Masoud nashibi

Street address
South kargar street, kamali street,loghman hakim hospital

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1333635445

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masoudnashibi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

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7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

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Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Masoud Nashibi

Position
Anesthesiologist

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available