

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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

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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 equals 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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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
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Person responsible for scientific inquiries

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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