Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of premedication with Tapentadol and Oxycodone sustain release for post operative pain control in Laparascopic cholecystectomy

Protocol summary

Study aim

Determination of the effect of premeditation with Oral tappentadol or oxycodone for the control of pain after laparoscopic cholecystectomy

Design

Three arm controlled randomised trial with blinded outcome assessment and a parallel group design of 60 patients, enrolled between August 2019 and March 2020. Randomization will be performed using RASS software and assignment ratio 1: 1: 1.

Settings and conduct

Participants who are referred to the operating room of Imam Reza Hospital of Tabriz University of Medical Sciences for laparoscopic cholecystectomy will be enrolled in the study via convenience sampling method. It would be impossible for research personnel involving with participants or analyzing the study results to adjust randomization or discern what product participants were receiving, ensuring true allocation concealment.

Participants/Inclusion and exclusion criteria

Inclusion criteria include all patients with cholelithiasis candidate for elective laparoscopic cholecystectomy and physical status 1 or 2 according to the American Society of Anesthesiologists Association's physical status classification. Exclusion criteria include the history of chronic consumption of other opioids or painkillers; history of cardiac, liver, respiratory or kidney disease; surgeries of more than one and a half hours and complicated surgeries.

Intervention groups

1- Tapontadol group: Receiving pre-treatment regimens of topentadol 75 mg oral mucosal anesthetics one hour prior to surgery with naproxin + metoclopramide 10 mg 2- Oxycodone group: Receiving pre-treatment regimens of oxycodone 15 mg oral an hour before surgery with naproxen + metoclopramide 10 mg 3- Control group: Without premedication regimen, naproxin + metoclopramide 10 mg

Main outcome variables

Pain intensity; first request for pain medication; amount of pain medication within 12 hours after surgery; pain duration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190618043923N2**
Registration date: **2019-07-08, 1398/04/17**
Registration timing: **prospective**

Last update: **2019-07-08, 1398/04/17**
Update count: **0**

Registration date

2019-07-08, 1398/04/17

Registrant information

Name

Dawood Aghamohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 1928

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aghamohammadi.d@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of premedication with Tapentadol and Oxycodone sustain release for post operative pain control in Laparascopic cholecystectomy

Public title

Effect of tapontadol and oxycodone in pain control

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with cholelithiasis undergoing elective laparoscopic cholecystectomy Physical status 1 or 2 according to the classification of the American Association of Anesthesiologists

Exclusion criteria:

Sensitivity to tapontadol or oxycodone History of chronic consumption of other opioids or analgesics Cardiac, liver, respiratory or renal disease Surgeries for over one and a half hours Complicated surgeries

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random Blocking Method and RASS Software, allocation concealment will ensured by sequentially numbered opaque sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, the main investigator, the person assessing the outcomes, and the person responsible for statistical analysis of the data will be kept blinded to assignment. Medications will be provided to the examiners in closed envelopes, which are labeled by a technician other than the original research members.

Placebo

Not used

Assignment

Parallel

Other design features

All patients will be under the same anesthesia method and will be operated by a surgeon.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Emam Reza Hospital, Golgasht St., West Arghavan Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5163995479

Approval date

2019-04-22, 1398/02/02

Ethics committee reference number

IR.TBZMED.REC.1398.106

Health conditions studied

1

Description of health condition studied

Patients with calculus of gallbladder candidated for laparoscopic cholecystectomy

ICD-10 code

K80.2

ICD-10 code description

Calculus of gallbladder without cholecystitis

Primary outcomes

1

Description

Pain intensity

Timepoint

Measuring the pain intensity at the beginning of the study (after surgery) and every two hours after the operation for up to 12 hours

Method of measurement

Visual analogue scale

2

Description

First request for pain medication

Timepoint

From the beginning of the study (after surgery) up to 12 hours after surgery

Method of measurement

Check patient records

3

Description

Amount of pain medication within 12 hours after surgery

Timepoint

From the beginning of the study (after surgery) up to 12 hours after surgery

Method of measurement

Check patient records

4

Description

Pain duration

Timepoint

From the beginning of the study (after surgery) up to 12 hours after surgery

Method of measurement

Self-declaration

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Receiving Pre-treatment regimens of one oral tablet of tapentadol 75 mg (NUCYNTA) branded by Collegium Pharmaceutical, Inc., an hour before surgery, with naproxen plus metoclopramide 10 mg

Category

Treatment - Drugs

2

Description

Intervention group 2: Receiving Pre-treatment regimens of one oral tablet of Oxycodone 15 mg (PHAROXY) branded by Collegium Pharmaceutical, Inc., an hour before surgery, with naproxen plus metoclopramide 10 mg

Category

Treatment - Drugs

3

Description

Control group: No premedication regimen which recieve naproxen plus metoclopramide 10 mg.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Dawood Aghamohammadi

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Emam Reza hospital, Golgasht Str., Azadi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

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Research Vice Chancellor, Tabriz University of Medical Sciences, Daneshgah Ave.

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dawood Aghamohammadi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work
Anesthesiology
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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