Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Comparative Study of the Effect of Apotel and Ketorolac Injection on Post-operative Pain Management and Decrease in Side Effects in Patients undergoing Laparoscopic Cholecystectomy Surgery

Protocol summary

Study aim

Comparative study of the effect of Apotel and Ketorolac injection on post-operative pain management and decrease in side effects in patients undergoing laparoscopic cholecystectomy surgery

Design

This study is a double blind clinical trial that will be done within 15 months. The statistical population includes cholecystectomy patients that using the systematic random allocation method, they will enter the research.

Settings and conduct

Imam Reza Hospital of Kermanshah - The laparoscopic cholecystectomy will be performed using the standard three-port technique. After the laparoscopic surgery, Patients will be divided into two groups so that the first group receiving Apotel and the second group receiving Ketorolac. (Instantly and 4 hours after surgery). Painkiller injections will begin into Recovery-room and by an anesthesiologist for patients. Patients in both intervention groups will not be informed of their medication. (1st Blinding). The treatment continue in the surgery ward by the specified nurse and under the supervision of a Principal Investigator. Patient follow-up within 24 hours; Evaluation of post-operative pain is performed in Instantly, 6, 12, 18 and 24 hours after surgery by an uninformed intern and by a visual Analogue scale (VAS). (2nd Blinding).

Participants/Inclusion and exclusion criteria

Entry requirements : history of cholecystitis, gallstone and gallbladder polyps. No-entry : lack of multiple trauma, lack of body mass index more than 35 and do not install the drain for the patient.

Intervention groups

The 1st intervention group will receive the Apotel and the 2nd intervention group will receive the Ketorolac. (Intravenous injection).

Main outcome variables

Pain, Dosages of painkiller, Nausea, Vomiting, Fever, Gastritis, Constipation, and Side-effects. (Unwanted side-effects are reported only if they occur).

General information

Reason for update

Acronym

ApoLac

IRCT registration information

IRCT registration number: **IRCT20200601047627N1**
Registration date: **2020-06-12, 1399/03/23**
Registration timing: **prospective**

Last update: **2020-06-12, 1399/03/23**
Update count: **0**

Registration date

2020-06-12, 1399/03/23

Registrant information

Name

Arash Azadmehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3427 6301

Email address

a_azadmehr@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Study of the Effect of Apotel and Ketorolac Injection on Post-operative Pain Management and Decrease in Side Effects in Patients undergoing Laparoscopic Cholecystectomy Surgery

Public title

The effect of painkillers on post-operative pain in gallbladder surgery.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with a history of cholecystitis Patients with biliary colic Patients with gallstone Patients with gallbladder polyp (more than 10 mm)

Exclusion criteria:

Pregnant and lactating women Patients with impaired renal or dialysis function Patients with heart disease and who should take warfarin during treatment Patients with contraindications for opioids use Patients with hemorrhage especially gastrointestinal Bleeding Patients with high blood pressure history or History of bloodshed Patients with abuse drug Patients with asthma, lung disease and allergies to NSAIDs Patients with multiple trauma. Patients with a history of psychiatric disorders or unable to communicate verbally Patients who need anti-emetic or antihistamines before or after surgery. Patients who should be treated with medication from one month before the surgery or during the study period. Patients who should be used the painkiller 7 days before the surgery. Patients who has a drain after surgery. Patients with a Body Mass Index of more than 35

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

The statistical population includes cholecystectomy patients that using the systematic random allocation method, they will be divided into two equal groups (In terms of the number of participants) and will enter the research. The division of patients will be based on a table of random numbers and the number of patients entering the study. After entering the PACU, patients will be divided into two groups so that the first group receiving Apotel and the second group receiving Ketorolac.

Blinding (investigator's opinion)

Double blinded

Blinding description

After the laparoscopic surgery, Patients will be divided into two groups so that the first group receiving Apotel and the second group receiving Ketorolac. (Instantly and 4 hours after surgery). Painkiller injections will begin into Recovery-room and by an anesthesiologist for patients. Patients in both intervention groups will not be informed of their medication. (1st Blinding). The treatment continue in the surgery ward by the specified nurse and under the supervision of a Principal Investigator. Patient follow-up within 24 hours; Evaluation of post-operative pain is performed in Instantly, 6, 12, 18 and 24 hours after surgery by an uninformed intern and by a visual Analogue scale (VAS). (2nd Blinding). Also patients will be given Preliminary information about VAS.

Placebo

Not used

Assignment

Parallel

Other design features

Patients will be monitored for pain intensity and The need for painkiller injections within 24 hours. If patients have a score more than 4 in VAS : (0-10), they will be given Pethidine. The nausea and vomiting of patients will be examined during 12 hours after operation in hour 2, 4, 8 and 12 after operation. The score will be given in quantitative terms from 0 to 2. The score will be as follows : 0 : have not, 1 : tolerable and 2 : Intense-unbearable; Also gastritis and constipation will be reported too. The score will be as follows : 0 : have not, 1 : Can be fixed and 2 : continuous-Intense. Fever will always be checked and an antibiotic will be injected if necessary. In this study, Metoclopramide will be injected in case of nausea and Ondansetron in case of vomiting. Also, in case of gastritis, first Pantoprazole and in case of lack of control and need for a second drug, intravenous Ranitidine will be used; In case of constipation, the patient will be given Pidrolax, and if constipation persists (score 2), a colonoscopy should be performed. Finally, the patient's pain rate, the dosages of the painkiller, nausea, vomiting, fever, gastritis and constipation will be reported in each patient's checklist, and the data will be encrypted and entered into statistical software after collection.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Kermanshah University of Medical Sciences, Shahid

Beheshti Blvd, Kermanshah Town.

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2020-05-12, 1399/02/23

Ethics committee reference number
IR.KUMS.REC.1399.218

Health conditions studied

1

Description of health condition studied
Cholecystitis

ICD-10 code
K80.13

ICD-10 code description
Calculus of gallbladder with acute and chronic cholecystitis with obstruction

Primary outcomes

1

Description
Check the rate of post-operative pain in both intervention group separately.

Timepoint
Instantly after surgery (Recovery - before the intervention begins) + 6, 12, 18 and 24 hours after surgery (Surgery wards - after the intervention begins).

Method of measurement
Visual analogue scale : (0-10)

2

Description
Check the dosages of the painkiller in both intervention group separately.

Timepoint
24 hours after surgery (Surgery wards - after the intervention).

Method of measurement
Register in the checklist : Millilitre (Quantitative)

3

Description
Check the prevalence rate of nausea in both intervention group separately.

Timepoint
2, 4, 8 and 12 hours after surgery (Surgery wards - after the intervention begins).

Method of measurement
Visual analogue scale : (0-2)

4

Description
Check the prevalence rate of vomiting in both intervention group separately.

Timepoint
2, 4, 8 and 12 hours after surgery (Surgery wards - after the intervention begins).

Method of measurement
Visual analogue scale : (0-2)

5

Description
Check the rate of fever in both intervention group separately.

Timepoint
2, 4, 8 and 12 hours after surgery (Surgery wards - after the intervention begins).

Method of measurement
Register in the checklist : Centigrade (Quantitative)

6

Description
Check the prevalence rate of gastritis in both intervention group separately.

Timepoint
2, 4, 8 and 12 hours after surgery (Surgery wards - after the intervention begins).

Method of measurement
Visual analogue scale : (0-2)

7

Description
Check the prevalence rate of constipation in both intervention group separately.

Timepoint
2, 4, 8 and 12 hours after surgery (Surgery wards - after the intervention begins).

Method of measurement
Visual analogue scale : (0-2)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Apotel recipient, 0 and 4 hours after surgery (2 times), PRN Pethidine, Intravenous injection.

Category
Treatment - Drugs

2

Description
Intervention group: Ketorolac recipient, 0 and 4 hours after surgery (2 times), PRN Pethidine, Intravenous

injection.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Ali Soroush

Street address

Imam Reza Hospital, Kermanshah Town.

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6301

Email

surgery_department@kums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

Kermanshah University of Medical Sciences, Shahid Beheshti Blvd., Kermanshah Town.

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Email

farid_n32@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Mohammadhossein Safari

Position

Clinical Research Associate

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Surgery Dept., Imam Reza Hospital, Kermanshah Town.

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Province

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Email

mohammadhosein.safari@kums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Arash Azadmehr

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Email

surgery_department@kums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Zhila Seyedi

Position
Head-nurse

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Imam Reza Hospital, Kermanshah Town.

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kermanshah

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Email
zhila.seyedi@kums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Unlimited

When the data will become available and for how long
Unlimited

To whom data/document is available
Unlimited

Under which criteria data/document could be used
Unlimited

From where data/document is obtainable
Send e-mail to : surgery_department@kums.ac.ir

What processes are involved for a request to access data/document
Receive an e-mail from the applicant - Refer the request to the Principal Investigator (PI) - Get a response from the PI - Send data to the applicant (In case of agreement).

Comments
Does not have.