Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The comparison of efficacy and side effects of IV(intravenous) Ibuprofen and intravenous Ketorolac in laparoscopic cholecystectomy patients.

Protocol summary

Study aim
Determining the effectiveness and side effects of intravenous ibuprofen and intravenous ketorolac in postoperative laparoscopic cholecystectomy pain control

Design
This study is a triple blind, controlled clinical trial with parallel groups

Settings and conduct
This was a randomized, triple-blind placebo-controlled trial at Imam Khomeini hospital in Ardebil. A total of 90 patients aged 20-60 years, undergoing laparoscopic cholecystectomy were randomized to receive either postoperative 800 mg IV-ibuprofen or 30 mg IV-Ketorolac or placebo (normal saline). Postoperative pain was managed with intravenous fentanyl (0.5 µ/Kg) as IV-PCA .

Participants/Inclusion and exclusion criteria
Study inclusion criteria: Patients undergoing laparoscopic cholecystectomy surgery at Imam Khomeini Hospital in Ardebil; At the age of 20-60 years; Consent to participate in research. Non inclusion criteria: All patients who have certain conditions, such as pregnancy and heart disease or kidney disease, etc., are excluded.

Intervention groups
Intervention Group 1: receive intravenous ibuprofen 800 mg. Control Group: receive placebo. Intervention Group 2: receive Intravenous ketorolac 30mg. All three groups receive medication at 0, 8, and 16 hours after surgery.

Main outcome variables
Abdominal pain; satisfaction of analgesia;, nausea and vomiting; shoulder pain; the using of opioids.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171003036530N2**
Registration date: **2018-09-03, 1397/06/12**
Registration timing: **retrospective**

Last update: **2018-09-03, 1397/06/12**
Update count: **0**

Registration date
2018-09-03, 1397/06/12

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 45 3358 2779
Email address
s.hoghughi@arums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-05, 1397/02/15

Expected recruitment end date
2018-07-21, 1397/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The comparison of efficacy and side effects of IV(intravenous) Ibuprofen and intravenous Ketorolac in laparoscopic cholecystectomy patients.

Public title
Comparison the effect of IV Ibuprofen and IV Ketorolac on post operation pain.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are undergoing laparoscopic cholecystectomy surgery at Imam Khomeini Hospital in Ardebil. Being at the age of 20 and 60 years old Patients who accept to participate in the research.

Exclusion criteria:

Pregnancy History of Asthma and Pulmunary disease History of heart disease History of CKD (chronic kidney disease) or dialysis History of GI (Gastrointestinal) bleeding History of HTN (hypertension) History of Anemia Using Warfarin Consumers simultaneously ACEI (angiotensin converting enzyme inhibitor) and Furosemide Drug dependence Allergic reaction to ibuprofen or NSAIDS or celecoxib

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is permuted block randomization in the individual unit. There are 90 sealed envelopes containing three types of code for example there are 30 code numbers for ibuprofen. The person in the operating room will pick an envelope for each patient without knowing the content and the drug will be administered by another person who is not aware of the drug's type.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The randomized order of interventions was concealed in opaque individual envelopes by the staff nurse, which were later opened by the nurse in recovery room at the end of surgery. The nurse prescribed drugs(ketorolac, ibuprofen or placebo in equal volume in similar syringes) without knowing patient's ID. The patient's data was collected every six hours without knowing the type of drugs. The principal investigator, patients and outcome assessmentor were blinded to group status, knowing only randomization group codes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardebil University of Medical Sciences

Street address

Daneshgah Ave

City

Ardebil

Province

Ardabil

Postal code

۵۶۱۸۹-۸۵۹۹۱

Approval date

2017-10-02, 1396/07/10

Ethics committee reference number

IR.ARUMS.REC.1396.136

Health conditions studied

1

Description of health condition studied

cholecystitis

ICD-10 code

k80

ICD-10 code description

cholecystitis

Primary outcomes

1

Description

abdominal pain

Timepoint

6,12 ,18, 24 hours after the operation, pain will be evaluated.

Method of measurement

The assessment of abdominal pain is based on the Visual Analogue Scale system.

2

Description

shoulder pain

Timepoint

6,12,18,24 hours after surgery

Method of measurement

The assessment of pain is based on the Visual Analogue Scale system.

3

Description

Nausea and Vomiting

Timepoint

6,12,18,24 hours after surgery

Method of measurement

The assessment is based on the N/V(Nausea and Vomiting)system.

4

Description

Loss of consciousness

Timepoint

6,12,18,24 hours after surgery

Method of measurement

The assessment is based on the Ramsay score.

Secondary outcomes

empty

Intervention groups

1

Description

The first Intervention group will receive a pain pump containing Fentanyl 100 ml and then intravenous Ketorolac 30 mg at intervals of zero, 8 and 16 hours after surgery.

Category

Other

2

Description

The second Intervention group will receive a pain pump containing Fentanyl and then intravenous Ibuprofen 80 mg at intervals of zero, 8 and 16 hours after surgery.

Category

Other

3

Description

Control group will receive a pain pump containing fentanyl and then intravenous Placebo at intervals of zero, 8 and 16 hours after surgery.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital in Ardebil

Full name of responsible person

Ali Amiri

Street address

Imam Khomeini Hospital, Ataee street, Janbazan square, Ardebil

City

Ardebil

Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr. Shahab Bohluli

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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

Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Somaye Hoghughi
Position
student
Latest degree
A Level or less
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
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
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
Title and more details about the data/document
All data will be published except the patient's ID(individual documents).
When the data will become available and for how long
Get started 6 months after printing results
To whom data/document is available
Researchers working in academia or university
Under which criteria data/document could be used
In order to use in any type of scientific research
From where data/document is obtainable
Email this address:sagarmehrmed@yahoo.com
What processes are involved for a request to access data/document
If the applicant send his request, after checking requested information, the data will be sent within a week.
Comments