

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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.hoghghi@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 Pulmonary 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 assessor 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
Ardabil
Postal code
۵۶۱۸۹-۸۵۹۹۱
Phone
+98 45 3325 1401
Email
sagarmehrmed@yahoo.com
Web page address
<http://www.arums.ac.ir/fa>

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Dr. Shahab Bohluli
Street address
Daneshgah Ave
City
Ardebil
Province
Ardabil
Postal code
۵۶۱۸۹-۸۵۹۹۱
Phone
+98 45 3352 2083
Fax
+98 45 3352 2082
Email
Shahab.bohloli@gmail.com
Web page address
<http://www.arums.ac.ir/fa>
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 Hoghghi

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Medical Education

Street address

Daneshgah Ave

City

Ardebil

Province

Ardebil

Postal code

56199-35661

Phone

+98 45333582779

Email

sagarmehrmed@yahoo.com

Latest degree

A Level or less

Other areas of specialty/work

Medical Education

Street address

Daneshgah Ave

City

Ardebil

Province

Ardebil

Postal code

56199-35661

Phone

+98 45 3358 2779

Fax

+98 45 3326 2140

Email

s.hoghghi@arums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ardebil University of Medical Sciences

Full name of responsible person

Dr Ali Mohamadian

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Daneshgah Ave

City

Ardebil

Province

Ardebil

Postal code

56199-35661

Phone

+98 45 3358 2779

Email

sagarmehrmed@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Ardebil University of Medical Sciences

Full name of responsible person

Somaye Hoghghi

Position

student

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