Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation efficacy and side effects of IV ibuprofen and IV acetaminophen in pain control after laparoscopic cholecystectomy

Protocol summary

Study aim
Evaluation efficacy and side effects of IV ibuprofen and IV acetaminophen in pain control after laparoscopic cholecystectomy

Design
This multicenter, randomized, triple-blind, placebo-controlled trial was conducted in 90 patients.1-receive Fentanyl in the form of pain-pomp and IV placebo every 8 hours for 30 patients.2-receive Fentanyl and Ibuprofen 800 mg Iv every 8h for 30 patients. 3-receive Fentanyl and Acetaminophen 1g Iv every 8h for 30 patients. Randomization: sealed envelopes.

Settings and conduct
This trial was conducted in 90 patients scheduled to undergo elective laparoscopic cholecystectomy at Imam Khomeini hospital in Ardebil within 6 months. For all patients embedded patient-controlled analgesia pump and after surgery were randomly assigned in three groups:1-receive Fentanyl in the form of pain-pomp and IV placebo. 2-receive Fentanyl and Ibuprofen 800 mg IV. 3-receive Fentanyl and Acetaminophen 1g IV.

Participants/Inclusion and exclusion criteria
Non-entry points: 1-Pregnancy 2-Have a history of asthma and other respiratory disease 3-Have a history of heart failure 4-Have a history of CRF or dialysis 5-Have a history of GI bleeding 6-HTN 7-Have a history of Anemia 8-Patients are taking warfarin 9-Patients are taking a combination of ACEI and furosemide 10-Tolerance or dependence to opioids 11-Allergy or hypersensitivity to ibuprofen , ASA ,NSAIDs, or COX2 inhibitor 12-Age less than 20 years old and more than 60 years old

Intervention groups
1-receive Fentanyl (60 ml in 100cc N/S) in the form of pain-pomp and IV placebo every 8 hours for 30 patients. 2-receive Fentanyl and Ibuprofen 800 mg Iv every 8h for 30patients. 3-receive Fentanyl and Acetaminophen 1g Iv every 8h for 30 patients.

Main outcome variables
Choose the more effective and less side effective drugs to pain control

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161024030479N2**
Registration date: **2018-06-07, 1397/03/17**
Registration timing: **retrospective**

Last update: **2018-06-07, 1397/03/17**
Update count: **0**

Registration date
2018-06-07, 1397/03/17

Registrant information

Name
Mahdiyeh Masoumzadeh

Name of organization / entity
Medical university of ardabil

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-23, 1397/05/01

Expected recruitment end date
2019-01-21, 1397/11/01

Actual recruitment start date
2016-11-21, 1395/09/01

Actual recruitment end date
2017-05-21, 1396/02/31

Trial completion date
empty

Scientific title
Evaluation efficacy and side effects of IV ibuprofen and IV acetaminophen in pain control after laparoscopic cholecystectomy

Public title
Evaluation efficacy and side effects of IV ibuprofen and IV acetaminophen in pain control after laparoscopic cholecystectomy.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients candidate for laparoscopic cholecystectomy Age 20 - 60 years old

Exclusion criteria:
1-Pregnancy Have a history of asthma and other respiratory disease Have a history of heart failure Have a history of CRF or dialysis Have a history of GI bleeding HTN Have a history of Anemia Patients are taking warfarin Patients are taking a combination of ACEI and furosemide Tolerance or dependence to opioids Allergy or hypersensitivity to ibuprofen, ASA, NSAIDs, or COX2 inhibitor Age less than 20 years old and more than 60 years old

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

Gender
Both

Phase
3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Actual sample size reached: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Sealed envelopes

Blinding (investigator's opinion)
Triple blinded

Blinding description
Prescribing medicine order the drug without information abute patient.Authorities collect data without informing the patient about the drug every six hours .Data evaluator is unaware about the type of drug given to each patient

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ardabil University of Medical Sciences

Street address
Ardabil University of Medical Sciences, Daneshgah st.

City
Ardabil

Province
Ardabil

Postal code
56189-85991

Approval date
2017-01-29, 1395/11/10

Ethics committee reference number
IR.ARUMS.REC.1395.89

Health conditions studied

1

Description of health condition studied
Cholecystit

ICD-10 code
K80

ICD-10 code description
Cholecystit

Primary outcomes

1

Description
Severity of pain in the surgical site

Timepoint
6, 12, 18 and 24 hours after surgery

Method of measurement
VAS system

Secondary outcomes

1

Description
Nausea and vomiting

Timepoint
6,12,18 and 24 hours after surgery

Method of measurement
N/V Score

2

Description
Shoulder pain

Timepoint

6,12,18 and 24 hours after surgery

Method of measurement

VAS

3

Description

Sedation

Timepoint

6,12,18 and 24 hours after surgery

Method of measurement

Ramsay score

Intervention groups

1

Description

First intervention group(control): for all patients embedded patient-controlled analgesia pump Fentanyl (60 ml in 100cc N/S) throughout the treatment period, patients also had access to Fentanyl (0.5 mg every 15 min) via patient-controlled analgesia or by patient request(PCA). Also receive IV placebo for a total of 3 doses:after the surgery, 8 and 16h after surgery.

Category

Placebo

2

Description

Second intervention group: embedded patient-controlled analgesia pump like control group and receive IV acetaminophen 1g for a total of 3 doses:after the surgery, 8 and 16h after surgery.

Category

Treatment - Drugs

3

Description

Third intervention group: embedded patient-controlled analgesia pump like control group and receive IV Ibuprofen 800mg for a total of 3 doses:after the surgery, 8 and 16h after surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital in Ardabil

Full name of responsible person

Dr Ali Mohammadian Erdi

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Imam Khomeini Hospital, Shahidan noiaghdam street

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Sponsors / Funding sources

1

Sponsor

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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

Ali Mohammadian Erdi

Position

Associate Professor

Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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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
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
Title and more details about the data/document
all the data will be publish After identifying people.name:Evaluation efficacy and side effects of IV ibuprofen and IV acetaminophen in pain control after laparoscopic cholecystectomy
When the data will become available and for how long
it Is accessible 3 months after printing results
To whom data/document is available
Every researcher In all disciplines can receive the information .
Under which criteria data/document could be used
If the data is useful for another study,Available to anyone specializing in this field.
From where data/document is obtainable
Responsive person is Mahdiyeh masoumzadeh with this way: masoumzadeh.med@gmail.com
What processes are involved for a request to access data/document
If the request is submitted to the email address, and the full introduction and explanation of the reason for the request,The data is sent within a week.
Comments