

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the Effect of Diclofenac and Pethidine on the severity of the Postoperative Pain of Laparoscopic Cholecystectomy in Opiate-Dependent and Non-Dependent Patients.

Protocol summary

Study aim

Comparing the Effect of Diclofenac Suppository with Intravenous Pethidine in Relieving Pain after Laparoscopic Cholecystectomy in Opioid-Dependent and Independent Patients

Design

In this single-blinded clinical trial with a control group, patients will enter the study with the convenience sampling method. Each group will be divided into two groups of 30 using block randomization. One subset of opioid-dependent and opioid-independent patients will be given 100 mg Diclofenac suppository and other subgroups will be given 25 mg pethidine injection intravenously.

Settings and conduct

This study will be taken place in Imam Reza hospital of Birjand. The drugs will be started one hour after recovery and will be repeated every 6 hours for the next 24 hours. The pain intensity will be assessed by a nurse who doesn't know the type of prescribed drug (single blind) using verbal rating scale (VRS).

Participants/Inclusion and exclusion criteria

-Inclusion criteria: Detected gallstones requiring surgery, Biliary sludge requiring surgery -Exclusion criteria: History of laparoscopic cholecystectomy; severe obstructive pulmonary disease; congestive heart failure (EF <20%); acute cholecystitis; gangrenous; empyema gallbladder; intestinal fistula in the biliary tract; obesity; pregnancy; ventriculoperitoneal shunt; previous abdominal surgery; the appearance of serious drug side effects; cirrhosis

Intervention groups

-Intervention group: One subset of opioid-dependent patients will be given 100 milligrams of Diclofenac as suppository through the rectal and other subgroups will be given 25 milligrams of pethidine via intravenous injection. -Control group: One subset of opioid-

independent patients will be given 100 milligrams of Diclofenac as suppository through the rectal and other subgroups will be given 25 milligrams of pethidine via intravenous injection.

Main outcome variables

The effect on pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140611018063N6**

Registration date: **2019-09-03, 1398/06/12**

Registration timing: **retrospective**

Last update: **2019-09-03, 1398/06/12**

Update count: **0**

Registration date

2019-09-03, 1398/06/12

Registrant information

Name

Ali Rajabpour Sanati

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-11-01, 1394/08/10

Expected recruitment end date

2016-04-30, 1395/02/11

Actual recruitment start date

2015-11-01, 1394/08/10

Actual recruitment end date

2016-04-30, 1395/02/11

Trial completion date

2017-06-30, 1396/04/09

Scientific title

Comparison of the Effect of Diclofenac and Pethidine on the severity of the Postoperative Pain of Laparoscopic Cholecystectomy in Opiate-Dependent and Non-Dependent Patients.

Public title

Diclofenac vs. Pethidine in cholecystectomy pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients with detected gallstones requiring surgery
patients with biliary sludge requiring surgery

Exclusion criteria:

history of laparoscopic cholecystectomy severe obstructive pulmonary disease congestive heart failure (EF <20%) acute cholecystitis gangrenous empyema gallbladder intestinal fistula in the biliary tract obesity pregnancy ventriculoperitoneal shunt previous abdominal surgery appearance of serious drug side effects cirrhosis

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Investigator

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

60 packed packs including 30 packs with a paper with letter "A" written on it and 30 packs with a paper with letter "B" written on it will be generated. Letter "A" represents the group receiving pethidine and letter "B" represents the group receiving diclofenac. Using block randomization and packed envelopes, the opioid dependent group will be divided randomly and equally into two groups: one will receive diclofenac and the other will receive pethidine. By block randomization and packed envelopes, the non-opioid dependent group will be divided randomly and equally into two groups: one group will receive diclofenac and the other group will receive pethidine. .

Blinding (investigator's opinion)

Single blinded

Blinding description

A nurse who does not know the prescribed drug uses the Verbal Rating Scale to evaluates the severity of pain in the patients.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Birjand University of Medical Sciences

Street address

NO. 37, 13th Modarres Street

City

Birjand

Province

South Khorasan

Postal code

9713754415

Approval date

2015-04-12, 1394/01/23

Ethics committee reference number

Ir.Bums.Rec.1394.244

Health conditions studied**1****Description of health condition studied**

pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

2**Description of health condition studied**

Cholelithiasis

ICD-10 code

K80

ICD-10 code description

Cholelithiasis

3**Description of health condition studied**

Acute cholecystitis

ICD-10 code

K81.0

ICD-10 code description

Acute cholecystitis

Primary outcomes

1

Description

The effect of prescribed drug on the severity of pain

Timepoint

measuring severity of the pain before intervention,
measuring severity of the pain 24 hours after the
initiation of the anti-pain drug (pethidine or diclofenac)

Method of measurement

verbal rating scale of pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: One subset of opioid-dependent patients will be given 100 mg Diclofenac suppository through the rectal starting from 1 hour after the recovery and repeated every 6 hours until 24 hours;

Category

Treatment - Drugs

2

Description

Intervention group: One subset of opioid-independent patients will be given 100 mg Diclofenac suppository through the rectal starting from 1 hour after the recovery and repeated every 6 hours until 24 hours;

Category

Treatment - Drugs

3

Description

Intervention group: one subset of opioid-dependent patients will be given 25 mg pethidine injection intravenously starting from 1 hour after the recovery and repeated every 6 hours until 24 hours;

Category

Treatment - Drugs

4

Description

Intervention group: one subset of opioid-independent patients will be given 25 mg pethidine injection intravenously starting from 1 hour after the recovery and repeated every 6 hours until 24 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Mostafa Behmanesh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr. Zarban

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Web page address

<http://www.bums.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand 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
Birjand University of Medical Sciences
Full name of responsible person
Ali Rajabpour-Sanati
Position
Medical Doctor
Latest degree
Medical doctor
Other areas of specialty/work
Neurosurgery
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Person responsible for scientific inquiries

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Person responsible for updating data

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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

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

Title and more details about the data/document

The entire statistical data from this study can be shared as needed based on the ethics committee's criteria.

When the data will become available and for how long

The results of this study, after publishing the results as a paper, will be published and shared.

To whom data/document is available

The data from this study will be available to all researchers.

Under which criteria data/document could be used

All academic researchers, in the form of research projects approved by the Ethics Committee, are allowed to access the data and perform the necessary analyzes on the documentation of this research.

From where data/document is obtainable

Applicants for obtaining documentation of this study can request information by email with the corresponding author.

What processes are involved for a request to access data/document

Researchers should send the research proposal code and ethics committee registrant code with the applicant

email.

Comments