Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Street address
NO. 37, 13th Modarres Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Zarban
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۹۷۱۷۸۵۳۵۷۷
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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

Contact

Name of organization / entity
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Full name of responsible person
Dr. Mohammad Yarani

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
General Surgery

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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