Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparison Between Sublingual Buprenorphine and Fentanyl Intravenous Pump for Postoprative Pain Relief After Open Cholecystectomy Surgery.

Protocol summary

Study aim

Comparison Between Sublingual Buprenorphine and Fentanyl Intravnous Pump for Postoperative pain relief after open Cholecystectomy Surgery

Design

The present study was a double blind clinical trial, in this study, 80 patients undergoing open Cholecystectomy were randomly divided into two groups and get into the study. the intervention group of Patients receiving Sublingual Buprenorphine Tablet and Placebo Pump and the control group received Placebo and intravenous Fentanyl Pump.

Settings and conduct

Trial will include patients undergoing open Cholecystectomy in Fatemi and Imam Khomeini hospitals in Ardabil city.The study is randomized simple randomized, The drugs were in separate packages and two envelopes and Patients and injectors have no knowledge of the contents of the envelope. In the intervention group, Sublingual Buprenorphine tablet administered 0.4 mg in 6, 12 and 18 hours recovey and placebo pump 50 cc normal saline in recovery and continued for 24 hours, if pain is not controlled, PCA is injected every 15 minutes.In the control group, Placebo Tablets were administered at 6,12 and 18 h,50 cc intravenous Fentanyl Pump (40 cc Fentanyl and 10 cc normal saline) embedded and half a cc (20 micrograms) of stat is injected and if the pain is not controlled, PCA is given by the Patient.then the VRS Score, Nausea, Vomiting, sedation of both groups were evaluated during the study times.

Participants/Inclusion and exclusion criteria

Inclusion criteria:ASA I و II,No other surgery, Age range 20 to 50 years. Exclusion criteria:History of opium and nerve medication use , ASA ≥ 3, Other surgery concurrent and complicated.

Intervention groups

Administration of Sublingual Buprenorphine and Placebo Pump to the intervention group,Administration of Placebo and Fentanyl Pump to control group.

Main outcome variables

Reduction of pain after open Cholecystectomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190901044665N1**
Registration date: **2019-10-30, 1398/08/08**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-30, 1398/08/08**
Update count: **0**

Registration date

2019-10-30, 1398/08/08

Registrant information

Name

parya bakhshpoori

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 13 4482 3993

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Between Sublingual Buprenorphine and Fentanyl Intravenous Pump for Postoprative Pain Relief After Open Cholecystectomy Surgery.

Public title

Comparison Between Sublingual Buprenorphine and Fentanyl Intravenous Pump for Postoprative Pain Relief After Open Cholecystectomy Surgery.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing open cholecystectomy Patients ASA 1and2 Patients who have no further surgery Age range 20 to 50 years

Exclusion criteria:

History of opium use Nervous drug history Active asthma ASA3 Other concurrent surgery Surgery lasted Complicated surgery

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

After patients were allowed to enter the study 80 patients were selected using simple sampling and the selected patients will be divided into two groups by random block design with 4 blocks. In this case all possible modes were considered to accommodate the letters AABB which is 6 modes. These 6cases were embedded in 6 papers and the papers were embedded in a black bag. Then we will make 20 paper bags every time. We draw a piece of paper write down the letters in it and we will add the next letter in the next drawing followed by the previous note we will have 80 letters in the end and at the time of sampling each person will receive a special letter in order of entry into the sample and so the people feel into one group .

Blinding (investigator's opinion)

Double blinded

Blinding description

The first group of 40 patients receiving Sublingual Buprenorphine Tablet and intravenous placebo Pump The second group will consist of 40 patients receiving Sublingual placebo Tablet and intravenous Fentanyl Pump. All Patients will be anesthetized by one-way treatment Protocol. Given that the study is randomly blocked,Buprenorphine and Placebo Buprenorphine and Fntanyl Pump and placebo pump separately and in two packs (Containing one pump and one Tablet) with specific codes B and A (Pack A containing Sublingual Buprenorphine and Placebo Pumps and and Pack B containing Placebo Tablets and Fentanyl Pumps) and The drug injector (Anesthetic Technician) has no information about the contents of the pack Select Pack A or B based on the Patient group. already specified are provided and every morning before the operation the number of Surgeries will be eliminated the same day.Start prescribing housing content envelopes after complete Cholecystectomy And it will be done in recovery. Patients will not be informed about the type of drug they receive.

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

Street address

Ardebil University of Medical Sciences, Office Complex End of University Street

City

Ardabil

Province

Ardabil

Postal code

8599156189

Approval date

2019-06-09, 1398/03/19

Ethics committee reference number

IR.ARUMS.REC.1398.103

Health conditions studied

1

Description of health condition studied

Comparison between Sublingual Buprenorphine and Fentanyl Intravenous Pump for postoperative pain relief after open Cholecystectomy Surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Reduction of pain after open Cholecystectomy
Timepoint
VRS score(Verbal Rating Score) in both groups at the time of study (in recovery,2,6,12,18 and 24) will be evaluated.
Method of measurement
Through the Score Verbal Rating Scale (VRS)

Secondary outcomes

1

Description
Nausea and Vomiting Score after open Cholecystectomy
Timepoint
Nausea and Vomiting in both groups at the time of study (in recovery,2,6,12,18 and 24) will be evaluated.
Method of measurement
By Scoring N&V Score

2

Description
Sedation Score after open Cholecystectomy
Timepoint
Sedation Score(Through the Ramsay relaxation Scale) in both groups at the time of study (in recovery,2,6,12,18 and 24) will be evaluated.
Method of measurement
Through the Ramsay relaxation Scale

Intervention groups

1

Description
In the intervention group, Sublingual Buprenorphine Tablet administered 0.4 mg in 6, 12 and 18 hours recovey and Placebo Pump 50 cc normal saline in recovery and continued for 24 hours, if pain is not controlled, PCA is injected every 15 minutes.
Category
Treatment - Drugs

2

Description
Control group:In the control group, Placebo Tablets were administered at 6,12 and 18 h,50 cc intravenous Fentanyl Pump (40 cc Fentanyl and 10 cc normal saline) embedded and half a cc (20 micrograms) of stat is injected and if the pain is not controlled, PCA is given by the patient.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemeh Training Center of Ardebil
Full name of responsible person
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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s.bohlooli@pharmacy.arums.ac.ir
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
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to Ethical Problems and Patient safety, The publish of IPD not applicable.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable