

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the analgesic efficacy of intraperitoneal bupivacain with intraperitoneal irrigation with bicarbonate following laparoscopic cholecystectomy

Protocol summary

Study aim

Comparison of the analgesic efficacy of intraperitoneal bupivacaine with intraperitoneal irrigation with bicarbonate following laparoscopic cholecystectomy

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

This study will be done in Rasool Akram hospital. Samples will be selected randomly. Researcher, analyzer and collector of samples do not be aware about the type of interventions . Patients aged 17 to 60 years old who are candidate for laparoscopic cholecystectomy with inclusion criteria such as lack of patients consent, addiction, allergic reaction, drug or alcohol abuse, chronic pain disorders, treating with steroids and conversion of laparoscopic cholecystectomy to open surgery. All surgeries will be performed by one surgeon .

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 17 to 60 years old who are candidate for laparoscopic cholecystectomy.
Exclusion criteria: Lack of patients consent, Opium use 24 hours before study, allergic reaction to each of study drugs, drug and alcohol abuse

Intervention groups

In this study, we will compare the two groups receiving intervention and one group receiving normal saline, so that the irrigation of the first intervention group will be done with bicarbonate 7.5 % intrapritoneal. Intervention group will receive 50 ml of bupivacaine 0.2% that is spread in bed of gallbladder .Control group only is irrigated intrapritoneal with normal saline

Main outcome variables

Pain following laparoscopic cholecystectomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180723040570N1**

Registration date: **2019-06-24, 1398/04/03**

Registration timing: **retrospective**

Last update: **2019-06-24, 1398/04/03**

Update count: **0**

Registration date

2019-06-24, 1398/04/03

Registrant information

Name

Nasim Nikoubakht

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8862 9854

Email address

nikoobakht.n@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

2017-07-23, 1396/05/01

Actual recruitment end date

2018-07-23, 1397/05/01

Trial completion date

2019-08-22, 1398/05/31

Scientific title

Comparison of the analgesic efficacy of intraperitoneal bupivacine with intraperitoneal irrigation with bicarbonate following laparoscopic cholecystectomy

Public title

Comparison of analgesia in postoperation pain of cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient consent Cholecystectomy for first time

Exclusion criteria:

Absence of addiction during 24 hours before surgery
Absence of allergic reaction to drugs
Absence of addiction of alcohol and drugs
Absence of chronic pain disorder
Absence of neurological disease or chronic usage of steroids

Age

From **17 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization by random allocation software

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients, main researcher, a person who collects the data, analyzer do not know about intervention and type of groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat ave.Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-06-10, 1397/03/20

Ethics committee reference number

IR.IUMS.REC 1396.32506

Health conditions studied

1

Description of health condition studied

cholecystectomy

ICD-10 code

K81.0

ICD-10 code description

Acute cholecystitis

Primary outcomes

1

Description

Pain that means anything bothers patients physically and mentally

Timepoint

Recovery and 2,8,24 hours after surgery

Method of measurement

visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: surgeon irrigates incision region and anastomosis with bupivacaine 0.2% through laparoscopy port then he waits 3 minutes and he empties gas intra abdominal completely

Category

Treatment - Drugs

2

Description

Intervention group: surgeon irrigates abdomen with 7.5 %bicarbonate in 1000 cc normal saline intraperitoneally . he changes patient position to right and left lateral , trendelenburg then supine so all of areas of peritoneum are irrigated. he waits 3 minutes then he empties intra abdominal gas and liquid.

Category

Treatment - Drugs

3

Description

Control group: Intraperitoneal irrigation with normal saline

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoolakram hospital

Full name of responsible person

Nasim nikoobakht

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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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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Nasim nikoobakht

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All documents

When the data will become available and for how long

One year after publication

To whom data/document is available

researchers of univercity

Under which criteria data/document could be used

All of analysyses

From where data/document is obtainable

Email :nnikobakht@yahoo.com Tel:00989125300531

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

After your request through email I answer it during one month

Comments