

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial comparing the effectiveness of intraperitoneal bupivacaine, acetazolamide and placebo on pain relief after laparoscopic cholecystectomy surgery

Protocol summary

Summary

Due to the importance of patients' pain after laparoscopic surgeries, this study will be conducted to compare the effectiveness of intraperitoneal bupivacaine, acetazolamide, and placebo on pain relief after laparoscopic cholecystectomy surgery. Patients admitted to Rasool Akram hospital with physical status I or II of the ASA system (American Society of Anesthesiologists); aged 20 to 60 years; and who is candidate for laparoscopic cholecystectomy surgery due to gallstones in 2015 will be included in study. Patients who do not consent to be included in the study, patients with bile duct problems, and who has acute cholecystitis will be excluded. Patients will be divided into three groups (each containing 20 patients) using block randomization system with foursome blocks. Group one will receive bupivacaine, Group two will receive intravenous acetazolamide, and Group three will receive intravenous saline as placebo. After surgery, patients' pain by visual analogue scale as well as paracetamol usage will be assessed. The mentioned parameters will be assessed at 1, 4, 8, 12 and 24 hours after surgery with a blind doctor. At the end, all information analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017032733159N1**
Registration date: **2017-06-06, 1396/03/16**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-06, 1396/03/16

Registrant information

Name

Alireza Negahi

Name of organization / entity

Iran university of medical sciences, Rasool Akram hospital

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

iran university of medical sciences

Expected recruitment start date

2017-05-01, 1396/02/11

Expected recruitment end date

2017-07-01, 1396/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparing the effectiveness of intraperitoneal bupivacaine, acetazolamide and placebo on pain relief after laparoscopic cholecystectomy surgery

Public title

Clinical trial comparing the effectiveness of intraperitoneal bupivacaine, acetazolamide and placebo on pain relief after laparoscopic cholecystectomy surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: having physical status I or II of the ASA system (American Society of Anesthesiologists); aged 20 to 60 years; who were candidate for laparoscopic cholecystectomy surgery due to gallstone. Exclusion criteria: Patients who do not consent to be included in the study; bile duct problems; acute cholecystitis; lack of ability to understand and use visual analogue scale (VAS); experience of sensitivity to NSAIDs and local anesthetics; class III and IV of ASA system; patients with choledocolitiasis; and drain in situ.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

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

Iran University of Medical Sciences, Hemat highway, Tehran, Iran

City

Tehran

Postal code

Approval date

2015-08-19, 1394/05/28

Ethics committee reference number

1394 8623215562

Health conditions studied

1

Description of health condition studied

Calculus of gallbladder without cholecystitis

ICD-10 code

K80.2

ICD-10 code description

Cholecystolithiasis Cholelithiasis Colic (recurrent) of gallbladder Gallstone (impacted) of: cystic duct gallbladder unspecified or without cholecystitis

Primary outcomes

1

Description

pain

Timepoint

just after surgery then 1, 4, 8, 12, and 24 hour after that

Method of measurement

visual analog scale

2

Description

paracetamol usage

Timepoint

just after surgery then 1, 4, 8, 12, and 24 hour after that

Method of measurement

according to patient documents

Secondary outcomes

1

Description

heart rate

Timepoint

just after surgery then 1, 4, 8, 12, and 24 hour after that

Method of measurement

documentd by doctor

2

Description

systolic blood pressure

Timepoint

just after surgery then 1, 4, 8, 12, and 24 hour after that

Method of measurement

documentd by doctor

3

Description

diastolic blood pressure

Timepoint

just after surgery then 1, 4, 8, 12, and 24 hour after that

Method of measurement

documentd by doctor

4

Description

respiratory rate

Timepoint

just after surgery then 1, 4, 8, 12, and 24 hour after that

Method of measurement
documented by doctor

Intervention groups

1

Description

intraperitoneal and local bupivacaine 0.5%. The maximum dose was 2 mg per kilogram. At the end of surgery and just one time

Category

Prevention

2

Description

0.5 mg per kg intravenous acetazolamide Once at the end of the surgery

Category

Prevention

3

Description

2 cc intravenous saline as placebo Once at the end of the surgery

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram hospital, Iran University of Medical Sciences

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Iran University of Medical Sciences

Full name of responsible person

Mr Adel

Street address

Iran University of Medical Sciences, Hemmet highway, Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Vice Chancellor for research of Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Surgery ward, Rasool Akram hospital

Full name of responsible person

Dr Alireza Negahi

Position

professor of general surgery

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Alireza Negahi

Position

Professor of general surgery

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Rasool Akram hospital

Full name of responsible person

Hamed Vaseghi

Position

Resident of general surgery

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty