

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Effect evaluation of interaperitoneal injection of bupivacaine on post-operative pain in laparoscopic cholecystectomy

Protocol summary

Summary

Background and aims: reduction of pain after Laparoscopic cholecystectomy. Inclusion criteria: 20-60 years old without diabetes mellitus, hypertension, congenital or acquired heart disease. Exclusion criteria: duration of surgery more than 2 hours; another operation at the same time; complication in or after operation. Intervention group received 0.5mg/kg intraperitoneal bupivacain 0.5 % after Laparoscopic cholecystectomy. Patients were evaluated in 0, 2, 4, 8, 12 and 24 hours after surgery. Primary outcome was pain reduction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012090910790N1**
Registration date: **2012-10-24, 1391/08/03**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-10-24, 1391/08/03

Registrant information

Name

Banafshe Valiyan Borujeni

Name of organization / entity

Ahwaz Jundishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 2422 2011

Email address

valian.b@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahwaz Jundishapour University of Medical Sciences

Expected recruitment start date

2011-05-22, 1390/03/01

Expected recruitment end date

2012-02-20, 1390/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect evaluation of interaperitoneal injection of bupivacaine on post-operative pain in laparoscopic cholecystectomy

Public title

Effect evaluation of interaperitoneal injection of bupivacaine on post-operative pain in laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 20-60 years old patients selected by American Society of Anesthesiologists (ASA) sorting. Exclusion criteria: Total Body Weight (TBW) <50 kg; chronic pain or using opioid (in recently month); history of abdominal aneurysm.

Age

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

Gender

Both

Phase

2

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

Ahwaz Jundishapour University of Medical Sciences

Street address

Ahwaz Razi hospital

City

Ahwaz

Postal code

Approval date

2012-06-14, 1391/03/25

Ethics committee reference number

536/3

Health conditions studied

1

Description of health condition studied

post-operative pain in laparoscopic cholecystectomy

ICD-10 code

K91.5

ICD-10 code description

Postcholecystectomy syndrome

Primary outcomes

1

Description

pain

Timepoint

0,1,2,8,12,24 hours after operation

Method of measurement

NRS

Secondary outcomes

1

Description

shoulder pain

Timepoint

0,1,2,8,12,24 hours after operation

Method of measurement

NRS

Intervention groups

1

Description

intervention group received, 0.5mg/kg intraperitoneal Bupivacain 0.25 % after Laparoscopic cholecystectomy

Category

Treatment - Drugs

2

Description

control group received 0.5 cc/kg , normal salin after Laparoscopic cholecystectomy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Street address

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahwaz Jundishapour University of Medical Sciences

Full name of responsible person

Dr. Mostafa Fegghi

Street address

Ahwaz Jundishapour University of Medical Sciences

City

Ahwaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahwaz Jundishapour 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

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Person responsible for general inquiries

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Web page address

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