

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of the effect of Injection of bupivacaine in reducing nausea and vomiting after laparoscopic cholecystectomy surgery

Protocol summary

Summary

In this study the effect of bupivacaine injection in the peritoneal cavity in reducing nausea and vomiting after laparoscopic cholecystectomy surgery have been compared with normal saline. In this randomized double blind clinical trial, 50 patients were enrolled in the study. Patients were in two groups. Inclusion criteria : 20 to 60 years ; ASA class I & II . Exclusion criteria : surgery longer than 2 hour ; Simultaneous surgery ; complication during or past surgery ; motion sickness . all patients were anesthetized with sodium thiopental 5mg/kg , atracurium .5 mg/kg , fentanyl 3mic/kg and midazolam .03 mg/kg . After surgery in the first group,.5 cc/kg saline 0/45% and in the second group 0/5cc/kg bupivacaine 0/5% was injected in the peritoneal cavity . nausea and vomiting were recorded at 1, 2, 6 and 12 hour after surgery with psycometric scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103156071N1**

Registration date: **2012-12-04, 1391/09/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-12-04, 1391/09/14

Registrant information

Name

Reza Akhoundzadeh

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2009-11-13, 1388/08/22

Expected recruitment end date

2010-11-13, 1389/08/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Injection of bupivacaine in reducing nausea and vomiting after laparoscopic cholecystectomy surgery

Public title

Effect of local anesthetics in reducing nausea and vomiting in laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : 20 to 60 years age ; ASA class I & II

Exclusion criteria : surgery longer than 2 hour ;

Simultaneous surgery ; complication during or past surgery ; motion sickness

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: 50

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
Ahvaz Jundishapur University of Medical Sciences

Street address
Shahrak Daneshgah , Golestan

City
Ahvaz

Postal code

Approval date
2010-11-13, 1389/08/22

Ethics committee reference number
ETH _ 013

Health conditions studied

1

Description of health condition studied
Nausea and Vomiting

ICD-10 code
K91.0

ICD-10 code description
Vomiting following gastrointestinal surgery

Primary outcomes

1

Description
Nausea and Vomiting

Timepoint
1 , 2 , 6 , 12 hour after surgery

Method of measurement
Psychometric Nausea and Vomiting Scale

Secondary outcomes

empty

Intervention groups

1

Description
In Intervention group 0/.5% bupivacaine 0/5 cc /kg was injected in peritoneal cavity at the end of surgery

Category
Treatment - Drugs

2

Description
In control group %0/45 saline 0/5 cc/kg was injected in peritoneal cavity at the end of surgery

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi Hospital

Full name of responsible person
Dr. Reza Akhoundzadeh

Street address
Felestin Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person
Dr Mostafa Fegghi

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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
Ahvaz Jundishapur 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***Phone**

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Postal code**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*