

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Evaluation of the effect of intraperitoneal injection of Bupivacain0.5% in post operation nausea and vomiting in laparoscopic cholecystectomy

#### Protocol summary

##### Summary

Background and aims In this clinical trial : reduction of post surgery nausea and vomiting 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 .age:20-60. 50 patient entered in our study . intervention group received, 0.5mg/kg intraperitoneal bupivacain 0.5 % after Laparoscopic cholecystectomy .patient evaluated in 1,2,6 and 12 hour after surgery .primary measurement is reduction of nausea and vomiting .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201110287928N1**

Registration date: **2012-04-22, 1391/02/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-04-22, 1391/02/03

##### Registrant information

##### Name

Hedieh Daneshyar

##### Name of organization / entity

Ahwaz Jundishapour University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1822 8446

##### Email address

daneshyar.h@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ahwaz Jundishapour University of Medical Sciences

##### Expected recruitment start date

2009-07-26, 1388/05/04

##### Expected recruitment end date

2010-04-24, 1389/02/04

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of intraperitoneal injection of Bupivacain0.5% in post operation nausea and vomiting in laparoscopic cholecystectomy

##### Public title

Evaluation of the effect of intraperitoneal injection of Bupivacain 0.5% in post operation nausea and vomiting in laparoscopic cholecystectomy

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

inclusion criteria: 20-60 years old without diabetes mellitus, hypertension, congenital or acquired heart dieses exclusion critreria: duration of surgery more than 2 hours, another operation at the same time, complication in or after operation

##### 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: 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

1

**Registry name**  
7928

**Secondary trial Id**  
Eth013

**Registration date**  
2012-01-04, 1390/10/14

## Ethics committees

1

**Ethics committee**

**Name of ethics committee**  
Ahwaz Jundishapour University of Medical Science

**Street address**  
Shaher daneshgah

**City**  
Ahvaz

**Postal code**

**Approval date**  
2011-06-27, 1390/04/06

**Ethics committee reference number**  
262/3

## Health conditions studied

1

**Description of health condition studied**  
nausea and vomiting resolve after laparoscopic cholecystectomy

**ICD-10 code**  
K91.5

**ICD-10 code description**  
Postcholecystectomy syndrome

## Primary outcomes

1

**Description**  
nausea

**Timepoint**

1hrs,2hrs,6hrs,12hrs after surgery

**Method of measurement**  
VAS

## Secondary outcomes

1

**Description**  
vomiting

**Timepoint**  
1hrs,2hrs,6hrs,12hrs after surgery

**Method of measurement**  
VAS

## Intervention groups

1

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

**Category**  
Treatment - Drugs

2

**Description**  
control group received 0.5 cc/kg , normal saline 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**  
Ahvaz Jundishapur University of Medical Science

**Full name of responsible person**  
Dr. Mostafa Feghhi

**Street address**  
Ahvaz Jundishapur 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**

Ahvaz Jundishapur University of Medical Science

**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**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Dr. Reza Akhond zade

**Position**

assistant professor

**Other areas of specialty/work****Street address**

Operation room, Imam Khomeini hospital

**City**

Ahwaz

**Postal code****Phone**

6193673166 -0098611222114

**Fax****Email**

rezaakh@hotmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Dr. Ahmad Reza Mohtadi

**Position**

assistant professor

**Other areas of specialty/work****Street address**

Imam khomini Hospital, Azadegan St.

**City**

Ahwaz

**Postal code****Phone**

+98 61 9367 3166

**Fax****Email**

mohtadi\_dr@yahoo.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Hedieh Daneshyar

**Position**

Anesthesiology Resident

**Other areas of specialty/work****Street address**

Imam khomini hospital, Azadegan St.

**City**

Ahwaz

**Postal code****Phone****Fax****Email**

dr.h.daneshyar@gmail.com

**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*