

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of pain severity after intraperitoneal injection of bupivacaine, morphine, hydrocortisone in laparoscopic cholecystectomy

Protocol summary

Summary

Aim: comparing the pain severity after laparoscopic cholecystectomy with intra-peritoneal injection of bupivacaine, morphine, hydrocortisone in 5th Azar hospital, 2016-2017 Design: double blind randomized phase 3 clinical trial, single center Study population: Cases candidate for cholecystectomy by laparoscopic method allocated in 3 groups Inclusion criteria: cases ages 20-50 years old with class I and II ASA Exclusion criteria: Consumption of opioids or sedative before operation, hematologic or neurologic diseases Intervention: intra-peritoneal injection of bupivacaine, morphine, hydrocortisone Intervention time: at the end of operation Outcome measures: Lowering the pain after operation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201703011264N9**

Registration date: **2017-05-27, 1396/03/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-27, 1396/03/06

Registrant information

Name

Sima Besharat

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

besharat@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Golestan University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pain severity after intraperitoneal injection of bupivacaine, morphine, hydrocortisone in laparoscopic cholecystectomy

Public title

Comparison of pain severity after intraperitoneal injection of bupivacaine, morphine, hydrocortisone in laparoscopic cholecystectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients candidate for laparoscopic cholecystectomy; age between 20 to 50 years; Class I and II ASA Exclusion criteria: Opioid consumption during 24 hours before the operation; Chronic fatigue syndrome; Inability to report pain; Steroid therapy; Neurologic diseases; Taking NSAIDs; Acute cholecystitis; Other kind of cholelithiasis (other than gall bladder); Hematological disorders; Neuromuscular diseases

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2-3

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

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Golestan University of Medical Sciences

Street address

Falsafi educational complex, 2 km from Gorgan to Sari

City

Gorgan

Postal code

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.GOUMS.REC.1396.3

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain reduction

Timepoint

Hours 0.5-1-4-8-16 after the surgery

Method of measurement

VAS scale

Secondary outcomes

1

Description

Time of bowel function onset

Timepoint

Hours 6-12-24 after the surgery

Method of measurement

Personal report

2

Description

Nausea and vomiting

Timepoint

Hours 0.5-1-4-8-12-16 after the surgery

Method of measurement

Personal report

3

Description

Time of oral nutrition

Timepoint

Hours 6-12-24 after the surgery

Method of measurement

Personal report

4

Description

Time of movement without help

Timepoint

Hours 6-12-24 after the surgery

Method of measurement

Personal report

Intervention groups

1

Description

Intra-peritoneal injection of 30 cc Bupivacaine 0.25%

Category

Treatment - Drugs

2

Description

Intra-peritoneal injection of 30 cc Bupivacaine 0.25% plus 2 milligram Morphine

Category

Treatment - Drugs

3

Description

Intra-peritoneal injection of 200 milligram Hydrocortisone

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

5th Azar hospital, Gorgan

Full name of responsible person

Dr. Maryam Zahedi Tabarestani

Street address

5th Azar Hospital, 5th Azar St, Gorgan city

City

Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Golestan University of Medical Sciences

Full name of responsible person

Dr. Hossein Taziki

Street address

Falsafi educational complex, Shastkola road, Gorgan

City

Gorgan

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, Golestan 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

Golestan University of Medical Sciences

Full name of responsible person

Dr.Maryam Zahedi Tabarestani

Position

Assistant of anesthesiology

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Golestan University of Medical Sciences

Full name of responsible person

Dr.Maryam Zahedi Tabarestani

Position

Assistant of anesthesiology

Other areas of specialty/work

Street address

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Fax

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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