

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

comparison of the effectiveness of intraperitoneal bupivacaine with clonidine on reduction of pain after laparoscopic cholecystectomy

Protocol summary

2018-05-25, 1397/03/04

Study aim

Evaluation the effect of intraperitoneal bupivacaine with oral clonidine on reduction of abdominal pain after laparoscopic cholecystectomy

Design

patients in group1 receive intraperitoneal normal saline as placebo patients in group2 receive intraperitoneal bupivacaine patients in group3 receive intraperitoneal bupivacaine and oral clonidine

Settings and conduct

study was done in Emam hospital of sari. patients and surgeon was blinded to the study

Participants/Inclusion and exclusion criteria

inclusion criteria: patients between 18-65 years old with cholecystitis or symptomatic cholelithiasis exclusion criteria: allergy history to anesthetic drug severe cardiac disease lung disease conversion to open cholecystectomy

Intervention groups

patients in group1 receive intraperitoneal normal saline as placebo patients in group2 receive intraperitoneal bupivacaine patients in group3 receive intraperitoneal bupivacaine and oral clonidine

Main outcome variables

abdominal pain shoulder pain nausea and vomiting pain killer consumption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180424039401N1**
Registration date: **2018-05-25, 1397/03/04**
Registration timing: **retrospective**

Last update: **2018-05-25, 1397/03/04**

Update count: **0**

Registration date

Registrant information

Name

farzad mokhtari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3324 4496

Email address

farzad_mokhtari_s@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-21, 1396/09/30

Expected recruitment end date

2018-05-21, 1397/02/31

Actual recruitment start date

2017-12-21, 1396/09/30

Actual recruitment end date

2018-05-21, 1397/02/31

Trial completion date

empty

Scientific title

comparison of the effectiveness of intraperitoneal bupivacaine with clonidine on reduction of pain after laparoscopic cholecystectomy

Public title

evaluation of effect of bupivacaine and clonidine on pain control after laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients between 18-65years old with cholecystitis
patients between 18-65years old with symptomatic

cholelithiasis

Exclusion criteria:
patients with Allergy history to the aneshtetic agent
severe cardiac disease severe lung disease patients with
conversion to open cholecystectomy

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **78**
Actual sample size reached: **78**

Randomization (investigator's opinion)
Randomized

Randomization description
patient selection will do by pick a card from a boxe with
78card . 26card with for group1, 26kard for group2 and
26card fot group3. surgeon and patients are blinded to the
study

Blinding (investigator's opinion)
Double blinded

Blinding description
patients selection will carry by head nurse with pick up a
card from a box with three type card(nubmer1, number2
and number3). patients and general surgeon are blinded
to the patients group. oral drug or placebo will give to
the patients by head nurse before surgery.
intraperitoneal drug or placebo will manage by
anesthesiologist

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of mazandaran University of
Medical Sciences

Street address
amirmazandarani street

City
sari

Province
Mazandaran

Postal code
4817843685

Approval date
2018-03-18, 1396/12/27

Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1396.1669

Health conditions studied

1

Description of health condition studied
acute cholecystitis

ICD-10 code
K80.0

ICD-10 code description
Calculus of gallbladder with acute cholecystitis

2

Description of health condition studied
chronic cholecystitis

ICD-10 code
K80.10

ICD-10 code description
Calculus of gallbladder with chronic cholecystitis without
obstruction

3

Description of health condition studied
cholelithiasis

ICD-10 code
K80

ICD-10 code description
Cholelithiasis

Primary outcomes

1

Description
abdominal pain

Timepoint
1 hour after operation. 6 hour after operation. 24 hour
after operation

Method of measurement
visual analogue score

2

Description
pain killer consumption

Timepoint
during 24 hours after surgery

Method of measurement
computing pain killer consumption

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: intrapetoneal bupivacaine 0.5% 20cc

Category

Treatment - Drugs

2

Description

Intervention group: 0.15 miligram tab clonidine 1.5 hour before surgery

Category

Treatment - Drugs

3

Description

Control group: 20cc normal saline as plasebo

Category

Placebo

4

Description

Control group: tab piridoxine 40 miligeram

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam hospital of sari

Full name of responsible person

Nasrin Rahmani

Street address

Amirmazandarani street

City

Sari

Province

Mazandaran

Postal code

۳۳۱۳۱-۴۸۱۶۶

Phone

+98 11 3336 1700

Email

farzad_mokhtari_s@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid saiedi

Street address

Amirmazandarani street

City

Sari

Province

Mazandaran

Postal code

۳۳۱۳۱-۴۸۱۶۶

Phone

+98 11 3336 1700

Email

name@domian.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sari University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Nasrin Rahmani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Moalem avenue

City

Sari

Province

Mazandaran

Postal code

48178-43685

Phone

+98 11 3324 4496

Email

farzad_mokhtari_s@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences
Full name of responsible person
Farzad Mokhtari
Position
Resident of surgery
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
Street address
Moalem square
City
Sari
Province
Mazandaran
Postal code
48178-43685
Phone
+98 11 3324 4496
Email
farzad_mokhtari_s@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Farzad Mokhtari
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
Street address
Moalem square
City
sari
Province
Mazandaran

Postal code
4817843685
Phone
+98 11 3324 4496
Email
name@domian.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

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When the data will become available and for how long

one week

To whom data/document is available

chief of study

Under which criteria data/document could be used

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From where data/document is obtainable

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What processes are involved for a request to access data/document

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Comments