Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Study aim
Evaluation the effect of intraperitoneal bupivacaine with oral clonidine on reduction of abdominal pain after laparoscopic cholecycectomy
Design
patients in group1 recieve intraperitoneal normal salin as placebo patients in group2 recieve intrapetitoneal bupivacaine patients in group3 recieve 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
iclusion criteria: patients between 18-65 years old with cholecyctitis or symptomatic cholelitiasis exclusion criteria: allergy history to anesthetic drug severe cardiac dsease lung disease conversion to open cholecyctectomy
Intervention groups
patients in group1 recieve intraperitoneal normal salin as placebo patients in group2 recieve intrapetitoneal bupivacaine patients in group3 recieve intraperitoneal bupivacaine and oral clonidine
Main outcome variables
abdominal pain shoulder pain nausia and vomiting pain killer consumtion

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
2018-05-25, 1397/03/04

Registrant information
Name
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Name of organization / entity
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Iran (Islamic Republic of)
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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 cholecyctectomy

Public title
evaluation of effect of bupivacaine and clonidine on pain control after laparoscopic cholecyctectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients bethween 18-65years old with cholecyctitis patients bethween 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 blined 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
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Majid saiedi
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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
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Person responsible for updating data

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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
.
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
.
From where data/document is obtainable
.
What processes are involved for a request to access data/document
.
Comments