Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Evaluation of using abdominal drainage after laparoscopic cholecystectomy in post operative pain

Protocol summary

Study aim
The effect of using abdominal drainage after laparoscopic cholecystectomy in postoperative pain in patients with cholelithiasis

Design
Two arm parallel group randomized trial with 60 patients in two groups. Study group with subhepatic drainage after laparoscopic cholecystectomy and control group without drains.

Settings and conduct
The study is conducted in Taleghani hospital in tehran.

Participants/Inclusion and exclusion criteria
Sixty patients enrolled in the study according to inclusion and exclusion criteria, and after consent they undergo laparoscopic cholecystectomy. Inclusion criteria:Patients scheduled for elective laparoscopic cholecystectomy due to gallbladder stones. Exclusin criteria: ASA Physical Status more than 3, renal insufficiency & history of coagulopathy.

Intervention groups
In the study group, sub-hepatic drainage is used. No drain is used in the control group.

Main outcome variables
Following the surgery, postoperative pain level was assessed using universal pain assessment tool (UPAT) at 0, 2, 4, 6, 12 and 24 hours after the operation. The postoperative morphine dose , the first analgesia consumption time and complications were noted.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130706013875N2**
Registration date: **2019-05-05, 1398/02/15**
Registration timing: **retrospective**
Last update: **2019-05-05, 1398/02/15**
Update count: **0**

Registration date
2019-05-05, 1398/02/15

Registrant information

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Farhad Fathi
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-23, 1397/05/01

Expected recruitment end date
2018-09-23, 1397/07/01

Actual recruitment start date
2018-07-23, 1397/05/01

Actual recruitment end date
2018-09-23, 1397/07/01

Trial completion date
2018-10-23, 1397/08/01

Scientific title
Evaluation of using abdominal drainage after laparoscopic cholecystectomy in post operative pain

Public title
Effect of abdominal drainage vs no drainage in laparoscopic cholecystectomy on post op pain management

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The patients who suffer from cholelithiasis The patients undergoing elective laparoscopic cholecystectomy

Exclusion criteria:

ASA Physical Status more thean 3 Renal insufficiency History of coagulopathy

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study through simple randomization method with the table of random numbers, patients assigned to two groups A balanced block method is used to allocate concealment so that the number of samples assigned to each of the groups is equal.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Next to Ayatollah Taleghani Hospital ,Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2018-05-15, 1397/02/25

Ethics committee reference number

IR.SBMU.MSP.REC.1397.195

Health conditions studied

1

Description of health condition studied

Gallbladder stone

ICD-10 code

K80.2

ICD-10 code description

Calculus of gallbladder without cholecystitis

Primary outcomes

1

Description

post operative pain

Timepoint

Post op time: 0-2-4-6-12-24 hour

Method of measurement

Universal Pain Assessment Tool

2

Description

Total morphine sulfate dose in the 24 hours after surgery

Timepoint

24 hours

Method of measurement

milligrams

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, the standard laparoscopic cholecystectomy operation was done, then the subhepatic drainage was inserted. The patients were transfered to recovery room and ward afterwards.

Category

Prevention

2

Description

Control group: In this group, the standard laparoscopic cholecystectomy operation was done. The patients were transfered to recovery room and ward afterwards. No drainage was inserted.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Taleghani hospital
Full name of responsible person
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Sponsors / Funding sources

1

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Name of organization / entity
Shahid Beheshti University of Medical Sciences
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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