Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

A clinical trial comparing the severity of abdominal pain after gallbladder removal from umbilical and subxiphoid ports in patients with symptomatic gallstone

Protocol summary

Study aim
To compare abdominal pain severity after gallstone removal from umbilical and subxiphoid ports in patients with symptomatic gallstone

Design
In this study, 76 eligible patients with symptomatic gallstone referring to Afzalipour medical center of Kerman were incorporated. Participants were randomly assigned into two intervention groups, and each participant was assigned a code.

Settings and conduct
The intervention in this double-blind study was performed in two groups in Afzalipour cre center in Kerman. Both groups underwent general anesthesia followed by laparoscopic cholecystectomy with four ports. In the first intervention group, the gallbladder was removed from the subxiphoid port, which is the conventional site. In the second group, the gallbladder was removed from the umbilical port.

Participants/Inclusion and exclusion criteria
Major inclusion criteria: presence of symptomatic gallstone and elective laparoscopic cholecystectomy surgery conducted in Afzalipour Care Center of Kerman. Major exclusion criteria: patients taking psychotropic drugs, including hypnotic and sedative drugs for any reason; epilepsy patients treated with antiepileptic therapy; and postoperative surgical complications, including wound bleeding and infection.

Intervention groups
Intervention group 1 (subxiphoid port): after the patient underwent general anesthesia, the gallbladder was removed from the subxiphoid port. Intervention group 2 (umbilical port): after the patient underwent general anesthesia, the gallbladder was removed from the umbilical port.

Main outcome variables
Postoperative abdominal pain severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170316033099N10**
Registration date: **2019-10-31, 1398/08/09**
Registration timing: **retrospective**

Last update: **2019-10-31, 1398/08/09**
Update count: **0**

Registration date
2019-10-31, 1398/08/09

Registrant information

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Mohammad Bagher Roozgar

Name of organization / entity
Birjand University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-06-22, 1396/04/01

Expected recruitment end date
2017-12-21, 1396/09/30

Actual recruitment start date
2017-06-22, 1396/04/01

Actual recruitment end date
2017-12-21, 1396/09/30

Trial completion date

2017-12-21, 1396/09/30

Scientific title
A clinical trial comparing the severity of abdominal pain after gallbladder removal from umbilical and subxiphoid ports in patients with symptomatic gallstone

Public title
Abdominal pain after gallbladder removal

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 20 and 60 years Presence of symptomatic gallstone Elective laparoscopic cholecystectomy surgery conducted in Afzalipour Care Center of Kerman Informed consent for participation in the study

Exclusion criteria:
Patients taking psychotropic drugs, including hypnotic and sedative drugs for any reason Epilepsy patients treated with antiepileptic therapy Patients who received pain relief for any reason Patients who had postoperative surgical complications, including wound bleeding and infection Acute cholecystitis patients whose pain initiated 72 hours earlier and did not respond well to medical treatment, thereby undergoing laparoscopic cholecystectomy

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **76**
Actual sample size reached: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
After the patients were recruited, they were assigned a code. Using the table of random numbers, the researcher allocated them to intervention group one or two.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study aim and procedure were explained to the patients. However, it remained untold as to which port to be used for the removal of their gallbladder. Patients and those who collected the data were blinded to the gallbladder removal port.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Kerman University of Medical Sciences

Street address
Haft Bagh Alavi Ave.

City
Kerman

Province
Kerman

Postal code
7616913555

Approval date
2017-06-12, 1396/03/22

Ethics committee reference number
IR.KMU.ACRS.REC.1396.1129

Health conditions studied

1

Description of health condition studied
Symptomatic gallstone

ICD-10 code
K80

ICD-10 code description
Cholelithiasis

Primary outcomes

1

Description
Postoperative abdominal pain severity

Timepoint
6 hours, 24 hours and 2 weeks after surgery

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1 (subxiphoid port): after the patient underwent general anesthesia, the gallbladder was removed from the subxiphoid port.

Category
Treatment - Surgery

2

Description
Intervention group 2 (umbilical port): after the patient underwent general anesthesia, the gallbladder was removed from the umbilical port.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour Care Center
Full name of responsible person
Dr. Ali Afsharizadeh
Street address
Imam Khomaini Highway
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7616913911
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr Abbas Pardakhti
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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
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Dr Ali Afsharizadeh
Position
General surgeon
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Deidentified Individual Participant Data Set

When the data will become available and for how long
when the article extracted from the research project is published and for 6 months

To whom data/document is available
researchers

Under which criteria data/document could be used
research purposes

From where data/document is obtainable
personal correspondence with the corresponding author

What processes are involved for a request to access data/document
Email to the corresponding author

Comments