Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation of the relation between prophylactic antibiotics and prevalence of surgical site infection in elective laparoscopic cholecystectomy in low-risk patients

Protocol summary

Study aim

Determining the effect of prophylactic antibiotics and the incidence of surgical site infection in elective laparoscopic cholecystectomy surgery in low-risk patients.

Design

A randomized controlled trial, Two-arm, parallel-group, phase 3, with blinded intervention and outcome assessment, on 122 patients. Randomization with permuted block randomization method.

Settings and conduct

All patients will be subjected to classic laparoscopic cholecystectomy in the 4-port method under direct supervision or by the university attendant at the educational center of Imam Reza Hospital. The preparation of the operation site will be performed according to the instructions of the operating room of Imam Reza (AS) hospital and with a 10% iodine solution. Gallbladder will be removed directly through the epigastric port. The duration of the operation, the opening of the gallbladder and the insertion of the drain during the operation will be recorded for each patient. After the operation, the patients will be discharged until significant recovery of pain and tolerance of the diet and if there is no fever and the wound is clean, with or without dressing, and according to the opinion of the respective attending physician. In this study, blinding will be double-blind, so that the patient and the person who collects the information (surgical resident) will not know about the group allocation.

Participants/Inclusion and exclusion criteria

All patients over the age of 18 who are candidates for laparoscopic cholecystectomy due to symptomatic gallstones, gall bladder polyps, chronic cholecystitis, or a history of biliary pancreatitis.

Intervention groups

Patients will be placed in the intervention group in the form of one gram of intravenous cefazolin in the serum received before the surgical incision or no prophylaxis. The control group will receive serum that does not contain antibiotics (placebo).

Main outcome variables

Prevalence of surface, deep, and intra-abdominal surgical site infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221230056987N1**
Registration date: **2023-05-09, 1402/02/19**
Registration timing: **retrospective**

Last update: **2023-05-09, 1402/02/19**
Update count: **0**

Registration date

2023-05-09, 1402/02/19

Registrant information

Name

Ali Nadjafi-semanani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3222 9129

Email address

sirius.ali@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date
2023-03-18, 1401/12/27
Actual recruitment start date
2022-06-22, 1401/04/01
Actual recruitment end date
2023-03-18, 1401/12/27
Trial completion date
2023-03-18, 1401/12/27

Scientific title
Evaluation of the relation between prophylactic antibiotics and prevalence of surgical site infection in elective laparoscopic cholecystectomy in low-risk patients

Public title
Evaluation of the relation between prophylactic antibiotics and prevalence of surgical site infection in elective laparoscopic cholecystectomy in low-risk patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Symptomatic Cholelithiasis Gallbladder polyps Chronic cholecystitis Hx of Biliary Pancreatitis
Exclusion criteria:
Breast Feeding mothers Allergy to Cephalosporins Hx of Chemotherapy Hx of CKD or Chronic Liver Diseases Diabetes Regular Steroid Consumption Acute Cholecyctitis Hx of Antibiotic consumption 5 days prior to intervention
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **122**
Actual sample size reached: **122**
Randomization (investigator's opinion)
Randomized
Randomization description
Intervention and Observation groups (A and B respectively) will be randomized in a block-to-block fashion, In which four block of 4 (AABB) is designed and randomly put after another until the designated sample size is reached. the aforementioned pattern will be used to distribute patients into a respected group
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be a double-blinded intervention so that the patient and the surgical team (residents and attending in charge of the patient) will not know about the allocation of the groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Birjand University of Medical Sciences
Street address
Birjand University of Medical Sciences, Ghafari Street, Birjand, South Khorasan, Iran
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۰۷۶
Approval date
2023-03-06, 1401/12/15
Ethics committee reference number
IR.BUMS.REC.1401.436

Health conditions studied

1

Description of health condition studied
Symptomatic Cholelithiasis
ICD-10 code
K80
ICD-10 code description
Cholelithiasis

2

Description of health condition studied
Gallbladder Polyp
ICD-10 code
K87
ICD-10 code description
Disorders of gallbladder, biliary tract and pancreas in diseases classified elsewhere

3

Description of health condition studied
Chronic Cholecyctitis
ICD-10 code
K80.10
ICD-10 code description
Calculus of gallbladder with chronic cholecystitis without obstruction

4

Description of health condition studied
Gallstone pancreatitis
ICD-10 code
K85.1
ICD-10 code description
Biliary acute pancreatitis

Primary outcomes

1

Description
Surgical site infection, superficial*
Timepoint
7 days after the operation
Method of measurement
Diagnosis of superficial surgical site infection according to the physician's opinion and based on clinical or paraclinical findings

2

Description
Surgical site infection, deep*
Timepoint
7 days after the operation
Method of measurement
Diagnosis of deep surgical site infection according to the physician's opinion and based on clinical or paraclinical findings

3

Description
Surgical site infection, Intra abdominal*
Timepoint
7 days after the operation
Method of measurement
Diagnosis of intra abdominal surgical site infection according to the physician's opinion and based on clinical or paraclinical findings

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in this group will receive prophylaxis in the form of one gram of intravenous cefazolin before surgical incision. All patients will be subjected to classic laparoscopic cholecystectomy in the 4-port method under direct supervision or by the university attendant at the educational center of Imam Reza Hospital. The preparation of the operation site will be performed according to the instructions of the operating room of Imam Reza (AS) hospital and with 10% iodine solution. Gallbladder will be removed directly without using endobag through epigastric port. The duration of the operation, the opening of the gallbladder or bleeding from the bed and the insertion of the catheter during the operation will be recorded for each patient. After the operation, the patients will be discharged with or without a drain and according to the opinion of the concerned doctor, until the significant recovery of pain and diet tolerance, and if there is no fever and the wound is clean.
Category
Treatment - Drugs

2

Description
Control group: patients in this group will not receive antibiotics before surgery and will instead receive a serum that does not contain antibiotics (placebo). All patients will be subjected to classic laparoscopic cholecystectomy in the 4-port method under direct supervision or by the university attendant at the educational center of Imam Reza Hospital. The preparation of the operation site will be performed according to the instructions of the operating room of Imam Reza (AS) hospital and with 10% iodine solution. Gallbladder will be removed directly without using endobag through epigastric port. The duration of the operation, the opening of the gallbladder or bleeding from the bed and the insertion of the catheter during the operation will be recorded for each patient. After the operation, the patients will be discharged with or without a drain and according to the opinion of the concerned doctor, until the significant recovery of pain and diet tolerance, and if there is no fever and the wound is clean.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hosital
Full name of responsible person
Ali Nadjafi-Semnani
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Ayatollah Taleghani Street, Imam Reza Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Mohammad Reza Miri
Street address
Birjand University of Medical Sciences, Education and Research Building, Second Floor, University Research and Technology Deputy
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Research@bums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand 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
Birjand University of Medical Sciences
Full name of responsible person
Ali Nadjafi-Semnani
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
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Position
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person
Ali Nadjafi-Semnani
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data will be made available in the form of SPSS files upon request

When the data will become available and for how long

The access period starts after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Overall evaluation of the research, re-analysis of the data, use of the data for further studies

From where data/document is obtainable

Electronic correspondence with the researcher, Dr. Ali Najafi Semnani, through the following email address Sirius.ali@gmailcom

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

Sending an email to the address provided and receive a response within 5 working days

Comments