

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The role of prophylactic antibiotics on surgical site infections in elective laparoscopic cholecystectomy in patients with symptomatic gallstone.

Protocol summary

Study aim

the role of prophylactic antibiotics in wound infection in selective laparoscopic cholecystectomy

Design

This study is a double-blind clinical trial with case-control, and randomized control grouped.

Settings and conduct

Patients with uncomplicated gallbladder stone who come to the Bamonar or Afzalipour Hospital of Kerman, in specified time who are candidates for laparoscopic cholecystectomy. These patients will be randomly divided into B and A groups. Group A patients received cefazolin antibiotics (dose of 1 gram) and group B received 10 cc isotonic normal saline, half an hour before surgery and two postoperative doses of 6 hours will be given intravenously. They will be checked 24 hours after surgery, and 4 to 7, 10, 15 and 30 days after surgery for wound infection.

Participants/Inclusion and exclusion criteria

Entry criteria: Age less than 75 years; No Immune deficiency disease; No history of Endoscopic Retrograde Cholangiography; Pancreatitis in the last week; Absence of antibiotics in one week prior to laparoscopy; No Common bile ducts stone; Non-detection of acute cholecystitis with gallstone stone; Lack of recognition of pancreatitis and cholangitis; Exit criteria: Age over 75 years; Impairment of immune system; history of Endoscopic Retrograde Cholangiography; Pancreatitis in the last week; Antibiotic use in one week before laparoscopy; Common bile duct stone; Diagnosis of acute cholecystitis with gallstone; Diagnosis of pancreatitis and cholangitis; In cases of severe bleeding; Or cases of bile duct and gallbladder rupture due to the need for post-operative antibiotics; All cases requiring a drain in the surgical site

Intervention groups

In the case group, prophylactic antibiotics were administered and in the control group placebo were Interventions

Main outcome variables

Surgical site infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180615040107N1**

Registration date: **2019-02-07, 1397/11/18**

Registration timing: **retrospective**

Last update: **2019-02-07, 1397/11/18**

Update count: **0**

Registration date

2019-02-07, 1397/11/18

Registrant information

Name

Amir Behzadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3439 2049

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

2018-03-21, 1397/01/01

Actual recruitment end date

2018-07-22, 1397/04/31

Trial completion date

2018-08-22, 1397/05/31

Scientific title

The role of prophylactic antibiotics on surgical site infections in elective laparoscopic cholecystectomy in patients with symptomatic gallstone.

Public title

prophylactic antibiotics on surgical site infections in elective laparoscopic cholecystectomy.

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with symptomatic gallstone Patients candidate for elective laparoscopic cholecystectomy Patient under 75 years old

Exclusion criteria:

Patients who received antibiotics in the few days before surgery Patients with CBD stone or cholecystitis Patients with a history of diabetes Patients with using drugs that affect the immune system

Age

To **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **76**

Actual sample size reached: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

By simple randomization in this study, these patients were randomly assigned to two groups A and B with random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients participating in the study, the principal researcher, physicians and nurses, data analyzers and outcome evaluators, were unaware of the allocation of each patient to the placebo group instead of antibiotics.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2018-05-19, 1397/02/29

Ethics committee reference number

IR.KMU.REC.1397.082

Health conditions studied**1****Description of health condition studied**

Surgical site infection

ICD-10 code

T81.4

ICD-10 code description

Infection following a procedure, not elsewhere classified

Primary outcomes**1****Description**

Surgical site infection involves redness and swelling of the wound or purulent discharge

Timepoint

24 hours after surgery and 4 to 7, 10 to 15 and 30 days after surgery

Method of measurement

Clinical

Secondary outcomes**1****Description**

Respiratory infection

Timepoint

24 to 72 hours after surgery

Method of measurement

Clinical

2**Description**

Fever& chills

Timepoint

24 to 72 hours after surgery

Method of measurement

Clinical

Intervention groups**1****Description**

Intervention group: In the first group, an antibiotic, cefazolin (one dose of 1 gram), will receive intravenous half an hour before the operation and two doses (1 gram) after surgery for 6 hours.

Category

Treatment - Surgery

2**Description**

Control group: In the second group, 10 cc of Isotonic normal saline will be given intravenously half an hour before surgery and two doses after surgery for a period of 6 hours.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Bahonar hospital

Full name of responsible person

Bahram Poorseyedi

Street address

Shahid Bahonar hospital, Qaraney St.

City

Kerman

Province

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7613747181

Phone

+98 34 3223 5011

Email

bahonarhospital@kmu.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Abass Pardakhti

Street address

Kerman, Ibn Sina Avenue, Somayeh Route, Research and Technology Department

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Email

vcr@kmu.ac.ir

Web page address

<http://kmu.ac.ir/fa/vcrt>

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

Amir Behzadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

No.31,B12 Alley, Farokh St., Golkhaneh St., khaneh esfahan

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Person responsible for scientific inquiries**Contact**

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Amir Behzadi

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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Determining the frequency of post-operative infection by age, determining the frequency of post-operative infection by sex, determining the frequency of post-operative infection based on the history of smoking. The total potential data can be shared after unidentifiable people

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academia and Scientific institutions

Under which criteria data/document could be used

For academic and medical research

From where data/document is obtainable

Amir Behzadi, Email: amirbehzady.ab@gmail.com

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

With sending the submitted proposal, I will send data within a month

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Amir Behzadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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