

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the efficacy of antibiotics on infectious complications after laparoscopic surgery for patients with Cholecystitis

Protocol summary

Summary

Laparoscopic cholecystectomy surgery component cleaning process is considered contaminated and the use of antibiotics in open surgery is recommended. Method for preventing nosocomial infections, we consider the effect of cefazolin administered in patients scheduled for elective laparoscopic cholecystectomy to assess. The candidates in the low-risk group. Patients aged 74-20 years with the condition of common bile duct stones, obstructive jaundice and acute cholecystitis are enrolled. In this clinical trial, 100 patients were selected, after obtaining informed consent from the patient and the surgeon accidentally by a nurse and without notice in the two groups (50 each) are prescribed and non-prescribed antibiotics. Criteria for surgical site infection: pain, swelling, redness, purulent discharge from the wound, diagnosed by the surgeon. Other infectious complications include intra-abdominal infections, peritonitis or abscess, surgical site after surgery and confirmed paraclinical experiments to be the other most commonly diagnosed as other infectious complications are reported .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013070413865N1**

Registration date: **2014-04-28, 1393/02/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-04-28, 1393/02/08

Registrant information

Name

Aliasghar Darzi

Name of organization / entity

Babol University of Medical Science

Country

Iran (Islamic Republic of)

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+98 11 3225 6285

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a.darzi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of reaserch and Technology of Babol University of Medical Sciences

Expected recruitment start date

2013-05-26, 1392/03/05

Expected recruitment end date

2015-03-25, 1394/01/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of antibiotics on infectious complications after laparoscopic surgery for patients with Cholecystitis

Public title

Comparison of the efficacy of antibiotics on infectious complications after laparoscopic surgery for patients with Cholecystitis

Purpose

Supportive

Inclusion/Exclusion criteria

(Inclusion criteria: age less than 75 years; absence of immuned efficiency diseases; lack of endoscopic retrograde cholangiopancreatography in recent weeks; antibiotics a week before laparoscopy; no common bile

duct stones; no diagnosis of acute cholecystitis with gallstones (based on clinical findings and clinical); diagnosis of pancreatitis and cholangitis; Exclusion criteria were: age over 75 years; the immune system is compromised; previous endoscopic retrograde cholangiopancreatography in recent weeks (due to antibiotics); antibiotics a week before laparoscopy; Common bile duct stones; acute cholecystitis with gallstones (based on clinical findings and clinical); pancreatitis and cholangitis; in cases where severe bleeding occurs during surgery or in the tear ducts bile and gallbladder due to needing antibiotics after surgery; all cases requiring surgical drains are in place)

Age

From **20 years** old to **74 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Babol University of Medical Sciences

Street address

Babol University of Medical Sciences-Ganjafruz
Street-Babol-Iran

City

Babol

Postal code**Approval date**

2013-05-14, 1392/02/24

Ethics committee reference number

2458

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

Chronic cholecystitis

ICD-10 code

K81.1

ICD-10 code description

Chronic cholecystitis

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

Surgical Site Infection

Timepoint

Five days after surgery

Method of measurement

Clinical

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

Respiratory Infection

Timepoint

24-72 hours after surgery

Method of measurement

Clinical

2**Description**

Fever and Chills

Timepoint

24-72 hours after surgery

Method of measurement

Clinical

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

Intervention group cefazolin 25 mg / Kg intravenous before transfer to the operating room by the nurse and two doses every 6 hours after surgery, the patient is injected.

Category

Treatment - Surgery

2**Description**

Regimen is not recommended for patients in the control group

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Babol University of Medical Sciences
Full name of responsible person
Street address
City
Babol

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Babol University of Medical Sciences- Ganjafrooz
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Deputy of Reaserch and Technology of Babol
University of Medical Sciences
Full name of responsible person
Dr Aliakbar Moghaddamnia
Street address
Babol University of Medical Sciences- Ganjafrooz
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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

Deputy of Reaserch and Technology of Babol University
of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Alieh Nikmanesh
Position
Student
Other areas of specialty/work

Person responsible for scientific inquiries

Contact

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General surgery
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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty