Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

Phone

+98 11 3225 6285

Email address

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 eficiency 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-Ganjafrooz 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
Street address
Babol University of Medical Sciences- Ganjafrooz Street- Babol- Iran
City
Babol
Postal code
Phone
+98 11 1225 6285
Fax
Email
Hidekey-2@yahoo.com
Web page address

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 Street-Babol-Iran
City
Babol
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
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Dr. Aliasghar Darzi
Position
General surgery
Other areas of specialty/work
Street address
Babol University of Medical Sciences-Ganj afrooz Street- Babol- Iran
City
Babol
Postal code
Phone
+98 11 1225 6285
Fax
Email
alidarzi@yahoo.com
Web page address

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