Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Infections after laparoscopic and open cholecystectomy; Ceftriaxone versus placebo; a randomized clinical trial

Protocol summary

Summary

Gall stone disease is one of the most frequent gastro-intestinal diseases ends up to surgery. Although laparoscopic cholecystectomy is accepted as treatment of choice in many countries worldwide, but its cost beneficiency and effectiveness in developing countries is controversial and is depended to multiple factors. Role of prophylactic antibiotics in prevention of infection is also controversial. In this study, we included 130 patients with cholelithiases with symptomatic acute /chronic cholecystitis or polyps of gall bladder admitted for surgery in Shohada E Tajrish Hospital between 2006 and 2008. They randomly were treated by either open or laparoscopic cholecystectomy. In each group, patients received cefteriaxon as prophylaxis of infection or isotonic sodium chlorides solution as placebo. In all patients, bile samples during surgery were collected and cultured. We compare patients according to demographic features, body weight ASA score, frequency of empyema, hydrops of gall bladder, cholecystitis, gall stones /polyps at time of admission, mean time of surgery and hospital stay, complications of surgery and infection rate. The aim of this study is to compare the role of surgery method and prophylactic antibiotic in reducing the complications (infection, rupture of gall bladder, spillage of bile /gallstone, need for subhepatic drains), and hospital stay period.

General information

Acronym

IRAC

IRCT registration information

IRCT registration number: **IRCT138805012220N1**
Registration date: **2009-11-01, 1388/08/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-11-01, 1388/08/10

Registrant information

Name

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Name of organization / entity

Shahid Beheshti University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research,Shahid Beheshti University of Medical Science

Expected recruitment start date

2006-08-11, 1385/05/20

Expected recruitment end date

2008-08-11, 1387/05/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Infections after laparoscopic and open cholecystectomy; Ceftriaxone versus placebo; a randomized clinical trial

Public title

Infection rate after cholecystectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1-aged 20-80, 2- cholelithiasis with acute/chronic cholecystitis [based on three of the following signs; abdominal pain in the upper right quadrant, Murphy's sign, leucocytosis > 10000/mm³, rectal temperature > 38 °C or < 36.5 °C plus, cholecystolithiasis (stones/sludge) or sonographic signs of cholecystitis (thickening and triple layer formation of the gall bladder wall) or polyps of gallbladder], 3- admitted in Shohada-e-Tajrish Hospital, Tehran, Iran for cholecystectomy between 2006 and 2008. Exclusion criteria: 1- Pregnant women, 2-patients with jaundice at the time of diagnosis, 3- coagulopathy, 4- coledocholithiasis, 5- portal hypertension, 6- diabetes mellitus, 7- immunosuppressive disorders, 8-previous biliary surgery, 9- biliary pancreatitis, 10- history of antibiotic consumption within one week before surgery, 11-allergic reaction/anaphylaxis to penicillin or cephalosporins, 12- any acute emergency interventions, 13- any contraindications for LC (previous history of abdominal surgery), 14 -conversion from LC to OC, 15- do not agree with conditions of study.

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

After explanation of surgical methods and study protocol we divided the patients into two groups by a table of random numbers. Group A undergone open cholecystectomy (OC) and group B undergone Laparoscopic Cholecystectomy (LC). Lab tests (CBC/diff, AST, ALT, serum billirubin, ALK-Ph) were checked for all patients before surgery. All surgeries were performed with the same surgery team who were expert in both methods. In each group patients randomly divided into two subgroups: first group received 1 gram Ceftriaxone during induction of anesthesia and the second group received 10 ml of isotonic sodium chlorides solution as placebo.drugs are injected by Anesthesiologist and neither the surgery team,who follow the patients,nor the patient know about the type of drug recieved . None of the patients received extra dosage of antibiotics (AB) during/after surgery. We compare patients according to demographic features, body weight ASA score, frequency of empyema, hydrops of gall bladder, cholecystitis, gall stones /polyps at time of admission, mean time of surgery and hospital stay, complications of surgery and infection rate, in each surgery method and compare the role of prophylactic antibiotic in reducing infection rate.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

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Shahid Beheshti University of Medical Sciences, Shahid Beheshti Blv. Daneshjoo Sqr. Velenjac

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Postal code

1985717443

Approval date

2007-06-04, 1386/03/14

Ethics committee reference number

125

Health conditions studied

1

Description of health condition studied

symptomatic gallstones

ICD-10 code

k80

ICD-10 code description

Cholelithiasis

2

Description of health condition studied

polyps of gallbladder

ICD-10 code

k82

ICD-10 code description

Other diseases of gallbladder

Primary outcomes

1

Description

complications of surgery method

Timepoint

during and one weak after surgery

Method of measurement

history and physical exam

2

Description

Spillage of bile/gallstone

Timepoint
during surgery
Method of measurement
observation

3

Description
need for Subhepatic drain
Timepoint
within one weak after surgery
Method of measurement
cc of secretion

4

Description
Mean operation time
Timepoint
period between begining and end of surgery
Method of measurement
minute

5

Description
bile culture results
Timepoint
one week after surgery
Method of measurement
culture results ,colony formation

6

Description
surgical site infection
Timepoint
within one weak after surgery
Method of measurement
history,physical exam

7

Description
Hospital Stay
Timepoint
period between admition for surgery and discharge
Method of measurement
days

Secondary outcomes

empty

Intervention groups

1

Description
single dose of ceftriaxone, 1 gr. during induction of anesthesia
Category
Prevention

2

Description
single dose of normal saline ,10 cc during induction of anesthesia
Category
Placebo

3

Description
laparoscopic cholecystectomy
Category
Treatment - Surgery

4

Description
open cholecystectomy
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Surgery, Shohada e Tajrish Hospital
Full name of responsible person
Mohamad Mozafar-Mohamad Reza Sobhiyeh, Farinaz Fattahi
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
Vice-Chancellor for Research,Shahid Beheshti University of Medical Science
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

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Other areas of specialty/work

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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