

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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 gastrointestinal diseases ends up to surgery. Although laparoscopic cholecystectomy is accepted as treatment of choice in many countries worldwide, but its cost beneficency 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 cholelithiasis 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 ceferiaxon 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

Mohamad Reza Sobhiyeh

###### Name of organization / entity

Shahid Beheshti University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2271 8001

###### Email address

mozafar@sbmu.ac.ir

##### 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/mm<sup>3</sup>, 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 bilirubin, 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 received. 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

**Street address**

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Shahid Beheshti Blv. Daneshjoo Sqr. Velenjac

**City**

Tehran

**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 week 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 beginning 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

##### **Street address**

Department of Surgery,Shohada e Tajrish Hospital,Tajrish Square

##### **City**

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## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

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

##### **Full name of responsible person**

Dr.M.Rahmati Rudsari

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Vice-Chancellor for Research,5th floor ,2nd block,Shahid Beheshti University of Medical Science,Velenjak,Tehran

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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*

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Resident of General Surgery

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Department of Surgery, Shohada e Tajrish

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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*