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 beneficience 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

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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**
None

**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 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**

### Ethics committee

**Name of ethics committee**
Shahid Beheshti University of Medical Sciences

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Tehran

**Postal code**
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**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 week 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 week after surgery

**Method of measurement**
- history, physical exam

**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

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**
- Department of Surgery, Shohada e Tajrish Hospital

**Full name of responsible person**
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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**
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**Full name of responsible person**
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**Grant name**
- empty

**Grant code / Reference number**
- empty

**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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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