

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Evaluation of the effect of antibiotics after surgery in patients with mild to moderate cholecystitis on the rate of infection at the site of surgery and deep infection

#### Protocol summary

##### Study aim

Evaluation of the effect of antibiotic administration after surgery in patients with mild to moderate cholecystitis on the rate of surgical site infection and deep infection

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 60 patients. Microsoft Excel software was used for randomization

##### Settings and conduct

Patients with mild and moderate acute cholecystitis referred to the emergency department of Sina and Amiralam hospitals in Tehran who are randomly divided into two groups after surgery. The process of randomization of patients into two groups by simple randomization using the Excel software is done by random numbers with a ratio of 1 to 1.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients over 18 years of age who are classified as mild or moderate cholecystitis. Non-inclusion criteria: Patients with common bile duct stones; Pregnant or lactating women; Patients' dissatisfaction to participate in the study; concurrent pancreatitis; Collongitis; patients with more than 48 interruptions from the diagnosis of cholecystitis to surgery; Patients with hepatobiliary system cancers

##### Intervention groups

Intervention group : (postoperative antibiotic therapy) are treated with oral ciprofloxacin 500 mg every 12 hours and metronidazole 250 mg every eight hours for up to 5 days after surgery. Patients who are unable to receive oral antibiotics will be treated with an intravenous antibiotic including ceftriaxone, 1 g every 12 hours and metronidazole 500 mg every 8 hours until PO is completed. Control group: Patients who do not receive postoperative antibiotic treatment.

##### Main outcome variables

The rate of infection at the surgical site; the rate of deep

infection

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201023049120N1**

Registration date: **2021-04-01, 1400/01/12**

Registration timing: **retrospective**

Last update: **2021-04-01, 1400/01/12**

Update count: **0**

##### Registration date

2021-04-01, 1400/01/12

##### Registrant information

##### Name

hamed akbari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4423 5283

##### Email address

dr.h.akbari82@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-21, 1398/01/01

##### Expected recruitment end date

2021-03-20, 1399/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effect of antibiotics after surgery in patients with mild to moderate cholecystitis on the rate of infection at the site of surgery and deep infection

**Public title**

Effect of Antibiotics in superficial and deep infection after cholecystectomy

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients who are classified as mild or moderate cholecystitis according to the Tokyo 2018 guideline Referred to the emergency department of Sina and Amir Alam hospitals from the March 21th, 2019 to March 20th, 2021 Age over 18 years

**Exclusion criteria:**

Patients with Severe cholecystitis (grade III) Patients who have had abdominal pain for more than 5 days Patients who have been diagnosed with common bile duct stones during preoperative or postoperative examinations Patients diagnosed with cholangitis include patients with concomitant pancreatitis Cirrhotic patients Patients with hepatobiliary system cancers Patients with acquired or primary immunodeficiency Patients with antibiotic susceptibility to beta-lactams Patients with cholecystitis since diagnosis acute mild or moderate for them until surgery more than 48 interruptions Pregnant or lactating patients Patients who did not consent to participate in this study

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, patients with mild to moderate acute cholecystitis after surgery were randomly divided to two separate groups: group A (receiving antibiotic therapy after surgery) and group B (not receiving antibiotic therapy after surgery). The patients are divided into two groups by simple randomization method and using Microsoft Excel 2013 software by random numbers (the admission code is randomized by the software) and with a ratio of 1 to 1. The surgeon doesn't aware of classification of patients into groups A and B and only the executor of the project is aware of the classification process. In fact, after the surgery, all the orders required by the patients are the responsibility of the executor of the project, and no one other than him/her is involved in the post-operation process and has no information.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Tehran University of Medical Sciences

**Street address**

Sina Hospital, Hasanabad square, Emam Khomeini street

**City**

Tehran

**Province**

Tehran

**Postal code**

1136746911

**Approval date**

2019-03-21, 1398/01/01

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1398.112

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

Cholecystitis

**ICD-10 code**

K81.0

**ICD-10 code description**

Acute cholecystitis

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

The rate of infection at the operation site

**Timepoint**

Up to 30 days after surgery(At the time of hospitalization daily and every two weeks thereafter)

**Method of measurement**

Presence of purulent discharge from the wound, positive culture of wound discharge sampled by sterile method with one or more of the following symptoms: pain, tenderness, local swelling, warmth or redness of the wound. The diagnosis of SSI is made by the patient's professor or resident.

## 2

### **Description**

The rate of deep infection

### **Timepoint**

Up to 30 days after surgery (At the time of hospitalization daily and every two weeks thereafter)

### **Method of measurement**

Presence of purulent discharge from the wound, positive culture of wound discharge sampled by sterile method with one or more of the following symptoms: pain, tenderness, local swelling, warmth or redness of the wound. The diagnosis of SSI is made by the patient's professor or resident.

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Patients in the intervention group (postoperative antibiotic therapy) are treated with oral antibiotics with ciprofloxacin 500 mg every 12 hours and metronidazole 250 mg every eight hours for up to 5 days after surgery. Patients who are unable to receive oral antibiotics will be treated with an intravenous antibiotic regimen including ceftriaxone, 1 g every 12 hours and metronidazole 500 mg every 8 hours until PO is completed.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Patients with mild to moderate acute cholecystitis who do not receive post operative antibiotic treatment and are evaluated for surgical site infection rate and deep infection within the first 30 days after surgery.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Sina hospital

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

Dr. Hamed Akbari

##### **Street address**

Hasanabad square; Emam khomeini street

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1136746911

##### **Phone**

+98 21 6634 8500

##### **Email**

hosp\_sina@sina.tums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Tehran University of Medical Sciences

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

Mohammad Ali Sahraeian

##### **Street address**

Headquarter of Tehran University of Medical Sciences; at the corner of Ghods street; Keshavarz boulevard

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1417653761

##### **Phone**

+98 21 8163 3685

##### **Fax**

##### **Email**

vcr@tums.ac.ir

##### **Grant name**

##### **Grant code / Reference number**

##### **Is the source of funding the same sponsor organization/entity?**

Yes

##### **Title of funding source**

Tehran University of Medical Sciences

##### **Proportion provided by this source**

100

##### **Public or private sector**

Public

##### **Domestic or foreign origin**

Domestic

##### **Category of foreign source of funding**

empty

##### **Country of origin**

##### **Type of organization providing the funding**

Academic

## **Person responsible for general inquiries**

#### **Contact**

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

Tehran University of Medical Sciences

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

Hossein Zabihi Mahmoudabadi

##### **Position**

Assistant Professor of Surgery

##### **Latest degree**

Specialist

##### **Other areas of specialty/work**

General Surgery

##### **Street address**

Sina Hospital; Hasanabad square; Emam Khomeini street

**City**

Tehran

**Province**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 6312 1220

**Email**

h.zabihi.dr@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Hossein Zabihi Mahmoudabadi

**Position**

Assistant Professor of Surgery

**Latest degree**

Specialist

**Other areas of specialty/work**

General Surgery

**Street address**

Sina Hospital; Hasanabad square; Emam Khomeini street

**City**

Tehran

**Province**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 6312 1220

**Email**

h.zabihi.dr@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Hossein Zabihi Mahmoudabadi

**Position**

Assistant Professor of. General Surgery

**Latest degree**

Specialist

**Other areas of specialty/work**

General Surgery

**Street address**

Sina Hospital; Hasanabad square; Emam Khomeini street

**City**

Tehran

**Province**

Tehran

**Postal code**

1136746911

**Phone**

+98 912 210 1070

**Email**

h.zabihi.dr@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

All information used for this study can be shared after making patients unidentifiable. Statistical information, data analysis, study method, findings and conclusions can also be shared

**When the data will become available and for how long**

For ever

**To whom data/document is available**

Every body

**Under which criteria data/document could be used**

Due to re-analysis the data and repeat the study

**From where data/document is obtainable**

Dr Hossein Zabihi Mahmoudabadi, hzabihim@tums.ac.ir

**What processes are involved for a request to access data/document**

Getting an ethical code, authenticating and collecting data and getting conclusions from the study in order to use it

**Comments**