Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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

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Tehran

Postal code
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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