Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the effect of prophylactic administration of first-generation cephalosporin antibiotics in decreasing of wound infection in patients candidates laparoscopic cholecystectomy

Protocol summary

Study aim

Evaluation the effect of prophylactic administration of first-generation cephalosporin antibiotics in decreasing the rate of wound infection in laparoscopic cholecystectomy in patients admitted to the Velayat hospital since 2016 to 2018

Design

In a double blind, randomized clinical trial, all patients candidate laparoscopic cholecystectomy at Velayat hospital during 2015-2017 entered to study. Patients are placed randomly (closed packet) in two groups. Before study informed consent form are completed by patients. Inclusion criteria are age<60. Exclusion Criteria are consumption antibiotic in 7 days ago, cholecyst in 6 past month, history of allergy or drug interactions with cephalosporin. In intervention group, 25 mg/kg cefazolin in per intervenes injection before surgery and 2 dose per 8 hours after surgery are prescribed, and control group with not receiving drug. At 24 hours after surgery, with close up wound dressing, they will be discharged in the absence of problems of nutrition, motility and fever. The patient should refer to remove stitches up to two weeks with having unusual pain symptoms, fever and chills, nausea and vomiting. Infection symptoms of surgery site (pain, swelling and redness, retraction purulent leak from incision site) are reported as SSI based on surgeon diagnosis. Peritoneal infection or abscess of Surgery site, respiratory infections and urinal infection are reported as other infectious complication after confirming by surgeon. The visual analogous scale of the pain is assessed at 24, 48 and 72 hours after surgery. Factors of age, sex, history of underlying diseases such as diabetes, high blood pressure, high blood sugar, heart disease, history of smoking, are documented.

Settings and conduct

In a double blind, randomized clinical trial, all patients candidate laparoscopic cholecystectomy at Velayat hospital during 2015-2017 entered to study. Patients are placed randomly (closed packet) in two groups. Before study informed consent form are completed by patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients candidate laparoscopic cholecystectomy; age<60. Exclusion criteria: consumption antibiotic in 7 days ago, cholecyst in 6 past months, Evidence of colaenitis or obstructive jaundice and biliary pancreatitis; systematic Corticosteroid therapy; reduced kidney function and liver failure; history of allergy; disorder in PT and PTT; drug interactions with cephalosporin; Breast feeding or pregnancy; History of biliary tract surgery or endoscopic retrograded cholangiography previous.

Intervention groups

In intervention group, 25 mg/kg cefazolin in per intervenes injection before surgery and 2 dose per 8 hours after surgery are prescribed, and control group with not receiving drug.

Main outcome variables

The visual analogous scale of the pain is assessed at 24, 48 and 72 hours after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171126037629N1**
Registration date: **2018-01-02, 1396/10/12**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-02, 1396/10/12**
Update count: **0**

Registration date

2018-01-02, 1396/10/12

Registrant information

Name

davoud mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 5800

Email address

d.mohammadi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of prophylactic administration of first-generation cephalosporin antibiotics in decreasing of wound infection in patients candidates laparoscopic cholecystectomy

Public title

Evaluation the effect of prophylactic administration of antibiotics in decreasing of wound infection in patients candidates laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: patients candidate laparoscopic cholecystectomy; age<60.

Exclusion criteria:

Exclusion criteria: consumption antibiotic in 7 days ago cholecyst in 6 past months Evidence of colaenitis or obstructive jaundice and biliary pancreatitis systematic Corticosteroid therapy reduced kidney function and liver failure history of allergy disorder in PT and PTT drug interactions with cephalosporin Breast feeding or pregnancy History of biliary tract surgery or endoscopic retrograded cholangiography previous.

Age

To **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **268**

More than 1 sample in each individual

Number of samples in each individual: **134**

In intervention group, 25 mg/kg cefazolin in per intervenes injection before surgery and 2 dose per 8 hours after surgery are prescribed, and control group with not receiving drug.

Randomization (investigator's opinion)

Randomized

Randomization description

Study is done as randomized, double blind on the individual by closed packet.

Blinding (investigator's opinion)

Double blinded

Blinding description

Study is done as randomized, double blind (investigator and patients) by closed packet (by assigning the letters A and B to the cards in the envelope and randomly selecting the envelopes by the patients). Before study informed consent form are completed by patients.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Qazvin university of medical sciences

Street address

Shahid Bahonar Blvd.

City

Qazvin

Province

Qazvin

Postal code

34139-96134

Approval date

2017-10-25, 1396/08/03

Ethics committee reference number

IR. QUMS.REC.1396.300

Health conditions studied

1

Description of health condition studied

gallbladder

ICD-10 code

K80.1

ICD-10 code description

Calculus of gallbladder with other cholecystitis

Primary outcomes

1

Description
Post operative pain
Timepoint
The pain is assessed at 24, 48 and 72 hours after surgery.
Method of measurement
The visual analogous scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 25 mg/kg cefazolin in per intervenes injection before surgery and 2 dose per 8 hours after surgery
Category
Treatment - Drugs

2

Description
Control group: Without drug regimen.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat Hospital
Full name of responsible person
Reza Noori Moghadam
Street address
Taavon Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
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Grant name
Vice chancellor for research, Qazvin University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin University of Medical Sciences
Proportion provided by this source
50
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
Qazvin University of Medical Sciences
Full name of responsible person
Reza Noori Moghadam
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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sub specialist thorax

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
That is secret according to informed consent.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not 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