

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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 colanitis 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)
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+98 28 3333 5800
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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 cholelithiasis 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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Qazvin

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Qazvin

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34139-96134

Phone

+98 28 3333 5800

Email

rajresearch95@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Reza Noori Moghadam

Street address

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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

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Davood Mohammadi

Position

sub specialist thorax

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

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Full name of responsible person

Reza Noori Moghadam

Position

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Latest degree

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Other areas of specialty/work

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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