Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Comparing the effects of post-operative prescription or non-prescription of ceftriaxone and metronidazole on infection reduction of patients operated with simple appendicitis: A clinical trial

Protocol summary

Summary

This clinical trial compares the effects of postoperative prescription or non-prescription of antibiotics on reduction of infection in patients operated for simple appendicitis in the surgery ward of Imam Reza Hospital of Birjand. The study is a single-blind randomized controlled trial with case and control groups where the participants will be unaware to which group they belong. The participants will include a total of 150 patients operated for acute appendicitis who lack chronic underlying disease and have a body mass index below 25. They will be allocated into case and control groups through simple randomization method so that everybody would have a similar chance of belonging to either the intervention or control groups. Both groups will receive antibiotics preoperatively, including ceftriaxone and metronidazole. Ceftriaxone will be prescribed in1 gram for adults and 50 mg per kg on a daily basis for children. Metronidazole will be prescribed 500 mg for adults and 35 mg per kg on a daily basis for children. Postoperatively, the cases will continue to take the antibiotics for 24 hours, while the controls will not receive any antibiotics. All patients will be followed during hospitalization and up to 14 days after surgery. They will be visited once a week after discharge (first and second weeks after surgery) by the surgeon in a clinic. The two groups will be examined with regard to infectious complications including wound infection, abdominal abscess, pelvic abscess, fever, and wound repair.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017031617756N12**
Registration date: **2017-03-29, 1396/01/09**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-03-29, 1396/01/09

Registrant information

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Mohammad Bagher Roozgar
Name of organization / entity
Birjand University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice-Chancellery for Research at Birjand University of Medical Sciences

Expected recruitment start date

2017-05-01, 1396/02/11

Expected recruitment end date

2017-06-01, 1396/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of post-operative prescription or non-prescription of ceftriaxone and metronidazole on

infection reduction of patients operated with simple appendicitis: A clinical trial

Public title
Effects of antibiotics on infection reduction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: age between 15 and 75 years; patients who have undergone surgery for acute appendicitis; patients with a and body mass index lower than 25; absence of advanced appendicitis (i.e., gangrene, perforation, peritonitis, or phlegmon) or normal appendicitis; lack of severe underlying or chronic diseases such as diabetes. Exclusion criteria: Unwillingness to continue participation
Age
From **15 years** old to **75 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single 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 Birjand University of Medical Sciences
Street address
Vice-chancellery of Research and Technology, Birjand University of Medical Sciences, Ghaffari St.,
City
Birjand,
Postal code
9717853577
Approval date
2017-02-12, 1395/11/24
Ethics committee reference number
Ir.bums.rec.1395.283

Health conditions studied

1

Description of health condition studied
Infection complications
ICD-10 code
T81.4
ICD-10 code description
Infection following a procedure, not elsewhere classified

Primary outcomes

1

Description
Wound infection
Timepoint
During hospitalization, first and second weeks after operation
Method of measurement
Physical examination

2

Description
Abdominal abscess
Timepoint
During hospitalization, first and second weeks after operation
Method of measurement
Physical examination and, if needed, by ultrasonography

3

Description
Pelvic abscess
Timepoint
During hospitalization, first and second weeks after operation
Method of measurement
Physical examination and, if needed, by ultrasonography

Secondary outcomes

1

Description
Fever
Timepoint
During hospitalization
Method of measurement
Thermometer

Intervention groups

1

Description
Control Group: They will receive antibiotics preoperatively, including ceftriaxone and metronidazole. Ceftriaxone will be prescribed as 1 gram for adults and

50 mg/kg/day for children. Metronidazole will be prescribed 500 mg for adults and 35 mg/kg for children. Postoperatively, the controls will not take any antibiotics.

Category

Treatment - Drugs

2

Description

Intervention group: They will receive antibiotics preoperatively, including ceftriaxone and metronidazole. Ceftriaxone will be prescribed as 1 gram for adults and 50 mg/kg/day for children. Metronidazole will be prescribed 500 mg for adults and 35 mg/kg for children. Postoperatively, the cases will continue to take the antibiotics for 24 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Sahar Samimi

Street address

Surgery ward, Imam Reza Hospital, Taleghani St.,

City

Birjand,

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellery of Research and Technology at Birjand University of Medical Sciences

Full name of responsible person

Dr. Tooba Kazemi

Street address

Vice-chancellery of Reasearch and Technology, Birjand University of Medical Sciences, Ghaffari St.,

City

Birjand,

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-Chancellery of Research and Technology at Birjand University of Medical Sciences

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

Person responsible for general inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Sahar Samimi

Position

Medical Student

Other areas of specialty/work

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Position

Student of Medicine

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Person responsible for updating data

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Position

PhD Candidate in Translation Studies

Other areas of specialty/work

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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