

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the effect of oral metronidazole and cefixime as prophylaxis in uncomplicated appendicitis in comparison with ceftriaxone and metronidazole injection

Protocol summary

Study aim

Evaluation of the effect of oral metronidazole and cefixime as prophylaxis in uncomplicated appendicitis in comparison with ceftriaxone and metronidazole injection

Design

Clinical trial with control group with mosaic group, randomized. Phase 2-3, on 200 patients with acute appendicitis, no blinding. Used for randomization by random block method

Settings and conduct

This clinical trial study is performed in Imam Hossein Hospital in Tehran. Patients with a diagnosis of acute appendicitis are included in the study. In the intervention group, metronidazole 500 mg with cefixime 400 mg orally and in the control group 500 mg metronidazole with 1 g of injectable ceftriaxone.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who were operated with clinical diagnosis of appendicitis. Exclusion criteria: Patients with complicated appendicitis (perforated and peritonitis), The underlying diseases (diabetes mellitus, acquired or intrinsic Immunodeficiency), Immunosuppressive drugs, Inability to follow patient

Intervention groups

Intervention group: Metronidazole 500 mg with cefixime 400 mg orally. Control group: Metronidazole 500 mg and one gram of ceftriaxone both injectable

Main outcome variables

Purulent discharge of the wound, Pain at the wound site, warmth in the wound, postoperatively compared in both groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160523028008N12**

Registration date: **2021-02-25, 1399/12/07**

Registration timing: **prospective**

Last update: **2021-02-25, 1399/12/07**

Update count: **0**

Registration date

2021-02-25, 1399/12/07

Registrant information

Name

Mohammad Faryadras

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3428 9706

Email address

m.faryadras@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-20, 1400/01/31

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral metronidazole and

cefixime as prophylaxis in uncomplicated appendicitis in comparison with ceftriaxone and metronidazole injection

Public title
The effect of antibiotics on reducing infection

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
patients are who were operated with clinical diagnosis of appendicitis's.
Exclusion criteria:
Patients with complicated appendicitis (perforated and peritonitis The underlying diseases (diabetes mellitus, acquired or intrinsic Immunodeficiency)
immunosuppressive drugs inability to follow patients

Age
From **10 years** old to **75 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

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 School of Medicine - Shahid Beheshti University of Medical Sciences
Street address
Faculty of Medicine, Shahid Beheshti University of

Medical Sciences, Arabi St., Yaman St., Chamran Highway

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2021-01-26, 1399/11/07

Ethics committee reference number
IR.SBMU.MSP.REC.1399.654

Health conditions studied

1

Description of health condition studied

Acute appendicitis

ICD-10 code

K35

ICD-10 code description

Acute appendicitis

Primary outcomes

1

Description

Purulent discharge of the wound

Timepoint

3,7 days, one month and three months after surgery

Method of measurement

Visual secretion

2

Description

Pain at the wound site

Timepoint

3,7 days, one month and three months after surgery

Method of measurement

asking the patient

3

Description

warmth in the wound

Timepoint

3,7 days, one month and three months after surgery

Method of measurement

Visual examination of the patient

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Metronidazole 500 mg with cefixime 400 mg orally
Category
Prevention

2

Description

Control group: Metronidazole 500 mg and one gram of ceftriaxone both injectable

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein Hospital

Full name of responsible person

Khosro Ayazi

Street address

Imam Hussein Hospital, Madani St, Nezam-Abad

City

Tehran

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1985717443

Phone

+98 21 2387 1000

Email

kh-ayazi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Behbahan University of Medical Sciences

Full name of responsible person

Khosro Ayazi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Behbahan University of Medical Sciences

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Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Position
Professor
Latest degree
Specialist
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

There is not a plan to make this available

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