

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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		Medical Sciences, Arabi St., Yaman St., Chamran Highway	
Public title	The effect of antibiotics on reducing infection	City	Tehran
Purpose	Treatment	Province	Tehran
Inclusion/Exclusion criteria		Postal code	1985717443
Inclusion criteria:	patients are who were operated with clinical diagnosis of appendicitis's.	Approval date	2021-01-26, 1399/11/07
Exclusion criteria:	Patients with complicated appendicitis (perforated and peritonitis The underlying diseases (diabetes mellitus, acquired or intrinsic Immunodeficiency) immunosuppressive drugs inability to follow patients	Ethics committee reference number	IR.SBMU.MSP.REC.1399.654
Age	From 10 years old to 75 years old	Health conditions studied	
Gender	Both	1	
Phase	2-3	Description of health condition studied	
Groups that have been masked	No information	Acute appendicitis	
Sample size	Target sample size: 200	ICD-10 code	
Randomization (investigator's opinion)	Randomized	K35	
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.	ICD-10 code description	
Blinding (investigator's opinion)	Not blinded	Acute appendicitis	
Blinding description		Primary outcomes	
Placebo	Not used	1	
Assignment	Parallel	Description	
Other design features		Purulent discharge of the wound	
Secondary Ids		Timepoint	
empty		3,7 days, one month and three months after surgery	
Ethics committees		Method of measurement	
1		Visual secretion	
Ethics committee		2	
Name of ethics committee		Description	
Ethics Committee of School of Medicine - Shahid Beheshti University of Medical Sciences		Pain at the wound site	
Street address		Timepoint	
Faculty of Medicine, Shahid Beheshti University of		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

Province

Tehran

Postal code

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

Street address

Shahid Beheshti University of Medical Sciences, Arabi St., Yaman St., Chamran Highway

City

Theran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2387 1000

Email

info@sbmu.ac.ir

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

Street address

Imam Hussein Hospital, Madani St, Nezam-Abad

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2387 1000

Email

kh-ayazi@gmail.com

Person responsible for scientific 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

Street address

Imam Hussein Hospital, Madani St, Nezam-Abad

City

Tehran

Province

Tehran

Postal code

1985717443

Phone
+98 21 2387 1000
Email
kh-ayazi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Khosro Ayazi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
General Surgery
Street address
Imam Hussein Hospital, Madani St, Nezam-Abad
City
Tehran
Province
Tehran
Postal code

1985717443
Phone
+98 21 2387 1000
Fax
Email
kh-ayazi@gmail.com

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