

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Efficacy of removing antibiotic therapy after appendectomy in surgical site infection in patients with imperforated appendicitis: A clinical trial

Protocol summary

Study aim

Determining the effect of eliminating antibiotic treatment after appendectomy on the prevention of surgical site infection in patients with non-perforated appendicitis

Design

Clinical trial with intervention and control groups, parallel groups, two-way blind, randomized using random number table

Settings and conduct

Patients diagnosed with appendicitis who undergo appendectomy and are diagnosed with non-perforated appendicitis are divided into two groups. 1: They receive a dose of antibiotics before the operation and do not take any more antibiotics after the appendectomy, and instead of antibiotics, they receive a placebo. 2: Receive a preoperative dose of antibiotics and receive the same antibiotics for up to 48 hours. patients and clinicians will not know whether patients are receiving antibiotics or placebo. Patients are examined on an outpatient basis for surgical site infections, one week after surgery, 2 weeks later, and 4 weeks later.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with a diagnosis of acute appendicitis referred to Ayatollah Mousavi Medical Center in Zanjan non-admission: immunosuppression, which are: From: 1- Corticosteroids 2- Cancer 3 -Diabetes 4- leukocyte insufficiency 5 -Aids and measles 6 - Nutrition

Intervention groups

Patients are randomly divided into two groups, one group after appendectomy did not receive antibiotics and the outcome will be measured and the outcome will be compared with the group taking antibiotics.

Main outcome variables

Purulent discharge from the wound, redness and inflammation of the wound, the presence of a mass under the skin that has purulent discharge with drainage, abdominal pain, fever

General information

Reason for update

Completion of the trial

Acronym

IRCT registration information

IRCT registration number: **IRCT20210319050743N1**

Registration date: **2021-03-24, 1400/01/04**

Registration timing: **prospective**

Last update: **2022-01-02, 1400/10/12**

Update count: **6**

Registration date

2021-03-24, 1400/01/04

Registrant information

Name

Mohammad Mohammadi arbaty

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3313 0000

Email address

mohammadarbati@zumc.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-07-06, 1400/04/15

Actual recruitment start date

2021-05-18, 1400/02/28

Actual recruitment end date

2021-10-30, 1400/08/08

Trial completion date

2021-11-29, 1400/09/08

Scientific title

Efficacy of removing antibiotic therapy after appendectomy in surgical site infection in patients with perforated appendicitis: A clinical trial

Public title

The effect of eliminating antibiotic treatment after appendectomy on surgical site infection

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with acute appendicitis referred to Ayatollah Mousavi Educational and Medical Center in Zanjan

Exclusion criteria:

Immunosuppression in patients undergoing appendectomy Diabetes AIDS Long-term use of corticosteroids Malnutrition Cancer Blood disease with leukocyte insufficiency

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **232**

Actual sample size reached: **232**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is block randomization. The size of the blocks is 8 people. Which includes 4 people from the intervention group and 4 people from the control group. The randomization unit is individual. Randomization tool is SAS statistical software. SAS statistical software and PLAN process are used to construct random sequences. For hiding, a random sequence is created first. Then, based on the sample size of the research, a number of envelopes with aluminum wrappers (In order not to see the contents of the envelopes) are prepared. Each random sequence is recorded on a card. The cards are placed in the envelopes of the letters, respectively. In order to maintain a random sequence, envelopes are numbered on the outer surface in the same way. Finally, the envelope lids are glued and placed inside the boxes, respectively.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients enter the study after obtaining informed written consent. Patients and the health care provider responsible for injecting the drug do not know if the patient is receiving medication or placebo. Also, the outcome assessor does not know at any stage of the examination that the patient initially received medication

or placebo.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Zanjan University of Medical Sciences

Street address

Gavazang Road, Zanjan University of Medical Sciences

City

Zanjan

Province

Zanjan

Postal code

4513956184

Approval date

2020-06-23, 1399/04/03

Ethics committee reference number

IR.ZUMS.REC.1399.115

Health conditions studied**1****Description of health condition studied**

Surgical site infection

ICD-10 code

T81.4

ICD-10 code description

Infection following a procedure

Primary outcomes**1****Description**

Purulent discharge from the wound

Timepoint

Clinical examination in The end of the first, second and fourth weeks After surgery

Method of measurement

History and clinical examination

2**Description**

Redness and inflammation of the wound

Timepoint

Clinical examination in The end of the first, second and

fourth weeks After surgery

Method of measurement

History and clinical examination

3

Description

stomach ache

Timepoint

Clinical examination in The end of the first, second and fourth weeks After surgery

Method of measurement

History and clinical examination

4

Description

Fever

Timepoint

Clinical examination in The end of the first, second and fourth weeks After surgery

Method of measurement

History and clinical examination

5

Description

Presence of a mass at the surgical site

Timepoint

Clinical examination in The end of the first, second and fourth weeks After surgery

Method of measurement

History and clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receive a placebo (distilled water) one cc every 12 hours for 48 hours after surgery

Category

Placebo

2

Description

Control group: They receive one gram of ceftriaxone every 12 hours + 500 mg of metronidazole every 8 hours for up to 48 hours after surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital in Zanjan

Full name of responsible person

Dr. Mohammad Mohammadi Arbati

Street address

Gavazang Road, Ayatollah Mousavi Hospital

City

Zanjan

Province

Zanjan

Postal code

4513956183

Phone

+98 24 3313 0000

Email

Mousavihospital@zums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Alireza Shaghli

Street address

Dr. Yousef Sabouti Blvd.Zanjan University of Medical Sciences

City

Zanjan

Province

Zanjan

Postal code

4513956184

Phone

+98 24 3301 8011

Email

info@zums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Mohammadi Arbati

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Gavazang Road, Ayatollah Mousavi Hospital

City

Zanjan

Province

Zanjan

Postal code

4513956183

Phone

+98 24 3313 0000

Email

mohammadarbati@zumc.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Mohammadi Arbati

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Gavazang Road, Ayatollah Mousavi Hospital

City

Zanjan

Province

Zanjan

Postal code

4513956183

Phone

+98 24 3313 0000

Email

mohammadarbati@zumc.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Mohammadi Arbati

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Gavazang Road, Ayatollah Mousavi Hospital

City

Zanjan

Province

Zanjan

Postal code

4513956183

Phone

+98 24 3313 0000

Email

mohammadarbati@zumc.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available