Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 arbati

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 24 3313 0000

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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 imperforated appendicitis: A clinical trial

Public title
The effect of eliminating antibiotic treatment after appendectomy on surgical site infectionn

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Alireza Shaghli
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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
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
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Person responsible for updating data

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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