

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparison of prophylactic antibiotic and immunostimulant in preventing wound infection and abases after abdominal surgery.

Protocol summary

Study aim

Comparison of the effect of prophylactic antibiotics and prophylactic antibiotics with golden immunostimulant in the prevention of postoperative cannelloni ulcers.

Design

60 patients who underwent abdominal surgery in the Vali-e-Asr Hospital during surgery were randomly and completely randomly selected from both males and females with informed consent of the patients and divided into two equal groups. The intervention group will receive a prophylaxis antibiotic with or without oral immunostimulants, orally, three times a day, one capsule, for 10 days. All patients are examined for signs of infection, inflammation, hematoma, and ulcers and serum openings when hospital discharge. In the control group, no immunostimulant is used.

Settings and conduct

60 patients who underwent abdominal surgery in the Vali-e-Asr Hospital during surgery were randomly and completely randomly selected from both males and females with informed consent of the patients and divided into two equal groups. The intervention group will receive a prophylaxis antibiotic with or without oral immunostimulants, orally, three times a day, one capsule, for 10 days. All patients are examined for signs of infection, inflammation, hematoma, and ulcers and serum openings before being hospitalized. In the control group, no immunostimulant is used.

Participants/Inclusion and exclusion criteria

Perforated appendix during iatrogenic surgery. Having infectious peritonitis. Removing digestive fistulas. Removing mesh.

Intervention groups

The intervention group will receive an intravenous antibiotic prophylaxis with or without oral immunostimulants, orally, three times a day, one capsule, for 10 days. In the control group: After abdominal surgery, antibiotics will receive prophylaxis for 10 days.

Main outcome variables

Prevention of post-surgical infections of cannamis wounds

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161017030336N6**

Registration date: **2019-04-15, 1398/01/26**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-15, 1398/01/26**

Update count: **0**

Registration date

2019-04-15, 1398/01/26

Registrant information

Name

Ghasem Habibi

Name of organization / entity

Islamic azad university

Country

Iran (Islamic Republic of)

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dr.habibi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-25, 1397/12/06

Expected recruitment end date

2019-04-25, 1398/02/05

Actual recruitment start date

2019-02-25, 1397/12/06

Actual recruitment end date

2019-04-25, 1398/02/05

Trial completion date

2019-04-25, 1398/02/05

Scientific title

Comparison of prophylactic antibiotic and immunostimulant in preventing wound infection and abases after abdominal surgery.

Public title

Comparison of prophylactic antibiotic and immunostimulant in preventing wound infection and abases after abdominal surgery.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Perforated appendix during iatrogenic surgery. Having infectious peritonitis. Having digestive fistulas. Having a protruding mesh.

Exclusion criteria:

Use of drugs that suppress the patient's immune system, such as contortionists or toxicity drugs.

Age

From **14 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description**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 Arak University of Medical Sciences

Street address

Basidj Bridge, Sadasht.

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2019-02-24, 1397/12/05

Ethics committee reference number

IR.ARAKMU.REC.1397.344

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

Acute appendicitis with generalized peritonitis

ICD-10 code

K35.2

ICD-10 code description

Acute appendicitis with generalized peritonitis

2**Description of health condition studied**

Acute appendicitis with localized peritonitis

ICD-10 code

K35.3

ICD-10 code description

Acute appendicitis with localized peritonitis

3**Description of health condition studied**

Acute appendicitis

ICD-10 code

K35.8

ICD-10 code description

Other and unspecified acute appendicitis

4**Description of health condition studied**

Infectious peritonitis

ICD-10 code

A54.2

ICD-10 code description

Gonococcal pelviperitonitis and other gonococcal genitourinary infections

5**Description of health condition studied**

Fistula of intestine

ICD-10 code

K63.2

ICD-10 code description

Fistula of intestine

6**Description of health condition studied**

Complications of surgical wound

ICD-10 code

T81.4
ICD-10 code description
Infection following a procedure

Primary outcomes

1

Description

Prevention of post-surgical infections of cannamis wounds

Timepoint

24 hours after surgery for up to 10 days after surgery

Method of measurement

Performing microbial culture from the site of surgery

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 patients who underwent abdominal surgery in the ward of surgery at Vali Asr Hospital in Arak, after prophylaxis antibiotic surgery with orphan medicinal product Gol-Dara, orally, three times a day, one capsule, for a period of Will receive 10 days. All patients are examined for signs of infection, inflammation, hematoma, and ulcers and serum openings before being hospitalized.

Category

Treatment - Drugs

2

Description

Control group: Control group: 30 patients undergoing abdominal surgery in the ward of surgery at Vali-Asr Hospital in Arak, and will receive prophylaxis after antibiotic surgery. All patients are examined for signs of infection, inflammation, hematoma, and ulcers and serum openings before being hospitalized.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital of Vali Asr Arak

Full name of responsible person

Dr. Ali Davoodi

Street address

Pardis of Arak University of Medical Sciences, Sardasht, Basidj Bidge, Arak, IR. IRAN

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Research Assistant of Arak University of Medical Sciences:Dr. Mohammad Arjomandzadegan

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Grant name

Grant code / Reference number

1397.344

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr.Ali Davoodi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Amir Reza Na'imi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Ghasem Habibi

Position

Research Assistant

Latest degree

Bachelor

Other areas of specialty/work

Traditional Medicine

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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

Not applicable

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