

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparative study of surgical site infection incidence in patients with perforated peptic ulcer that undergo primary intention versus delayed primary(tertiary) intention

Protocol summary

Study aim

Incidence comparison of surgical site infection in each groups of study

Design

Randomised clinical trial with two different groups , parallel groups , single blinded , randomised and designed for 80 patients , randomisation with random number table

Settings and conduct

Patients with perforated peptic ulcer at imam reza hospital of kermanshah will divided into two groups and undergo different intentions and finally the outcome of each intention will compared. Patients and someone who divide them will not know which intention goes to whom

Participants/Inclusion and exclusion criteria

No entry if ; there is underlying disease , recent use of antibiotics , recent hospitalization , use of immunosuppressive drugs or corticosteroids

Intervention groups

The first group will undergo primary intention and the second group will undergo delayed primary intention

Main outcome variables

Incidence of surgical site infection in patients with primary intention ; Incidence of surgical site infection in patients with delayed primary intention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210508051227N1**

Registration date: **2022-03-11, 1400/12/20**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-11, 1400/12/20**

Update count: **0**

Registration date

2022-03-11, 1400/12/20

Registrant information

Name

arash koohibibidehkordi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3427 6300

Email address

arash_koohi_ar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-08-21, 1401/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of surgical site infection incidence in patients with perforated peptic ulcer that undergo primary intention versus delayed primary(tertiary) intention

Public title

Comparative study of surgical site infection incidence in patients with perforated peptic ulcer that undergo primary intention versus delayed primary(tertiary) intention

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with perforated peptic ulcer Presence of peritonitis clinical sign that confirmed by surgeon Presence of paraclinical findings that confirms peritonitis

Exclusion criteria:

Presence underlying disease like HIV , Diabetes , hepatitis , collagen vascular disease Use antibiotics for one recent month Hospitalization for 3 recent month People with BMI more than 30 Using drugs like immunosuppressive or corticosteroid

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Numbers with random sequences are generated by PASS software and random number table and are encrypted into envelopes. The patient is then asked to choose one of the envelopes completely randomly (this part is done by one of the operating room staff or a doctor who does not know the details of the plan) and based on the number in the envelopes, the surgical method is selected.

Blinding (investigator's opinion)

Single blinded

Blinding description

Primary intention method is considered as the basic method and delayed primary intention method is considered as the intervention method. Due to the assignment of encrypted envelopes containing numbers determining the type of surgery to each patient, as a result, patients are unaware of the type of intention method assigned to them.(Before presenting the envelopes to the patients, both types of surgical procedures and their complications will be explained to the patients and the consent of both surgeries will be taken from them). Considering that the intervention is a type of surgical procedure that the difference between them is in the kind of surgical incision and unlike the medical interventions, the patient will notice the surgical method after regaining consciousness according to the explanations given to him before the surgery in relation to the two existing types of surgery. As a result, blinding is performed only until surgery.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Kermanshah University of Medical Sciences

Street address

No 20 , 11 mtri dovvom alley , mousa kalantari ave

City

kermanshah

Province

Kermanshah

Postal code

6715746687

Approval date

2021-03-09, 1399/12/19

Ethics committee reference number

IR.KUMS.REC.1400.257

Health conditions studied

1

Description of health condition studied

Perforated peptic ulcer

ICD-10 code

K27.1

ICD-10 code description

Acute peptic ulcer, site unspecified, with perforation

Primary outcomes

1

Description

incidence of surgical site infection

Timepoint

14 days

Method of measurement

observation

Secondary outcomes

empty

Intervention groups

1

Description

In this group, delayed primary intention is performed. In this way, after the perforation is repaired, all the layers of the abdominal wall are closed after surgery, and only the skin of the abdominal wall remains open for 5 days,

and then it is sutured.

Category

Treatment - Surgery

2

Description

In this group, the primary intention method is performed. In this way, after perforation repair, all layers of the abdominal wall, including the skin, are sutured in the operating room immediately after surgery.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imamreza hospital

Full name of responsible person

Ali Toolabi

Street address

next to the medical school, Parastar blvd

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75333 - 67427

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+98 83 3427 6300

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irhk@kums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Sasan Jamshidi

Street address

Shahidbehshiti Blvd , Kermanshah University of Medical Science

City

Kermanshah

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6714869914

Phone

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Mcollege@kums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Ali Toolabi

Position

medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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