

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Delay versus early closure of skin in laparotomy incision in perforated peptic ulcer patients

Protocol summary

Study aim

By determining whether the results of the delay closure and early closure of the skin are different in peptic ulcer perforation surgery, it is possible to determine the optimal method in this field .

Design

Two arm parallel group randomized clinical trial without blinding

Settings and conduct

58 patients who are undergoing open surgery in Imam Hossein Medical Center, Tehran in 1399 due to perforated peptic ulcer disease will be selected. Individuals enter the study if they sign a written consent form and will be randomly divided to two groups of early closure and delayed closure. In the early closure group , the skin is closed at the end of the operation, and in the delayed closure group, the skin is closed within several days from the surgery. Finally, the data of duration of stay, side effects including infection at the site of laparotomy and mortality rate will be collected and compared .

Participants/Inclusion and exclusion criteria

The including criteria is laparotomy due to perforated peptic ulcer disease and excluding criteria are lack of willingness to participate in the study, underlying diseases such as diabetes and end stage kidney disease and cancer, the use of immune-suppressive drugs, and corticosteroids .

Intervention groups

Patients are divided into two groups: Early closure and Delayed closure. In early closure group, the skin is closed at the end of the operation, and in the delayed closure group, the skin is closed several days after the surgery.

Main outcome variables

Age, gender, location of injury, method of repair; duration of hospitalization; complications; mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200404046936N1**

Registration date: **2020-04-15, 1399/01/27**

Registration timing: **prospective**

Last update: **2020-04-15, 1399/01/27**

Update count: **0**

Registration date

2020-04-15, 1399/01/27

Registrant information

Name

Arash Mohammadi Tofigh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7758 5851

Email address

arash_mtofigh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-04, 1399/02/15

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Delay versus early closure of skin in laparotomy incision in perforated peptic ulcer patients

Public title

“Delay versus early closure of skin in laparotomy incision in perforated peptic ulcer surgery”

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Laparotomy due to perforated peptic ulcer

Exclusion criteria:

Diabetes End stage renal disease Taking immune-suppressive drugs Corticosteroids consumption Cancer

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

Table of random numbers

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 Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Evin

City

تهران

Province

Tehran

Postal code

1985717443

Approval date

2019-07-02, 1398/04/11

Ethics committee reference number

IR.SBMU.MSP.REC.1398.313

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

Infection of surgery site

Timepoint

3, 7 and 14 days after surgery

Method of measurement

inspection

2

Description

Duration of stay

Timepoint

From the surgery to discharge from ward

Method of measurement

Days

3

Description

Mortality rate

Timepoint

From the surgery to 30 days after the surgery

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the skin is sutured and closed at the end of surgery.

Category

Treatment - Surgery

2

Description

Control group: the skin is left open at the end of surgery and closed within several days after the surgery.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Medical Center

Full name of responsible person

Arash Mohammadi Tofigh

Street address

Shahid Madani st.

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shervan Family

Position

Resident of general surgery

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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No 10 , 19 ave, Kharazm st, Shahrak gharb

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Arash Mohammadi Tofigh

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Email

shervanf@gmail.com

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All the data of the patients participating in the study will be shared after the study.

When the data will become available and for how long

Data sharing will be possible 6 month after publishing the results.

To whom data/document is available

Researchers working in academic and scientific institutions.

Under which criteria data/document could be used

In order to continue the study and increase the number of samples and develop the study

From where data/document is obtainable

Arash Mohammadi Tofigh via email address
arash_mtofigh@yahoo.com shervan family via email
address shervanf@gmail.com

What processes are involved for a request to access data/document

Immediately after receiving the request, the applicant's person or institution will be examined and the requested file will be sent within a week

Comments