Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Questionaire

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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1985717443
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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
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
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Person responsible for updating data

Contact

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Full name of responsible person
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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