

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Evaluation of the effect of subcutaneous implantation of Corrugated drain in reducing the incidence of surgery side infection in patient with midline incision

Protocol summary

Study aim

Evaluation of the effect of subcutaneous implantation of Corrugated drain in reducing the incidence of surgery side infection in patient with midline incision

Design

Clinical trial with control group, with parallel groups, without blinding, randomized, on 79 patients. The random function of Excel 2013 software has been used for randomization.

Settings and conduct

Patients who are urgently treated for acute peritonitis and have a TSF above 20 mm with a midline incision in Sina Hospital are followed up for two months and then the incidence of SSI (surgical site infection) is compared in two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: Biliary peritonitis or fecal peritonitis; Subcutaneous fat thickness of more than 20 mm; Surgery with midline incision. Non-inclusion criteria are: Age of under 18 years old and over 70 years old; Surgery with any incision except midline incision; Pregnant and Immune deficiency patients; Subcutaneous fat thickness of less than 20 mm; Other types of peritonitis

Intervention groups

Intervention group: Patients who underwent emergency abdominal open surgery and pre-suture carogit implantation. Control group: Patients who underwent emergency open abdominal surgery and were routinely sutured.

Main outcome variables

Surgical site infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201022049115N1**

Registration date: **2021-05-14, 1400/02/24**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-14, 1400/02/24**

Update count: **0**

Registration date

2021-05-14, 1400/02/24

Registrant information

Name

hossein zabihi mahmoudabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8808 3689

Email address

hzabihim@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2021-05-21, 1400/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of subcutaneous implantation of Corrugated drain in reducing the incidence of surgery

side infection in patient with midline incision

Public title

Evaluation of the effect of Carrogated drain in reducing SSI

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with acute peritonitis who have undergone acute midline incision surgery Patients with biliary peritonitis, fecal peritonitis, or patients with obvious pus in the peritoneal cavity Patients with subcutaneous fat thickness of more than 20 mm

Exclusion criteria:

Patients under 18 years old and over 70 years old
Patients who do not consent to participate in the study
Patients who undergo surgery with incisions other than midline incisions (McBurney incision, cochlear incision, paramedin incision, etc.)
Pregnant patients
Immune deficiency patients (patients with HIV positive serology, patients undergoing immunosuppressive therapy and patients undergoing any chemotherapy in the last 3 months)
Patients for whom any other implant except drain is implanted (including meshplasty, etc.)
Patients who do not visit the clinic at the appointed times for follow up
Patients with a subcutaneous fat thickness of less than 20 mm
Patients with other types of peritonitis (pancreatic peritonitis, etc.)

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **158**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who undergo emergency abdominal surgery with midline incision in Sina Hospital with a diagnosis of peritonitis and have a TSF above 20 mm are randomly allocated to the groups based on random numbers by Microsoft Office Excel 2013 software.

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 Tehran university of Medical Sciences

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1111111111

Approval date

2020-04-12, 1399/01/24

Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1398.005

Health conditions studied

1

Description of health condition studied

Acute abdomen

ICD-10 code

R10.0

ICD-10 code description

Acute abdomen

2

Description of health condition studied

Acut peritonitis

ICD-10 code

K65

ICD-10 code description

Peritonitis

3

Description of health condition studied

Biliary peritonitis

ICD-10 code

K65

ICD-10 code description

Peritonitis

4

Description of health condition studied

Fecal peritonitis

ICD-10 code

K65

ICD-10 code description

Peritonitis

Primary outcomes

1

Description

Surgical site infection

Timepoint

Evaluation of surgical site infection daily during hospitalization and also at the time of patients' visit to the hospital clinic up to 30 days after surgery

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with subcutaneous fat thickness greater than 20 mm who underwent pre-suture subcutaneous Corrugated drain implantation in emergency open midline laparotomy for 3 to 5 days after surgery .

Category

Treatment - Surgery

2

Description

Control group: Patients with subcutaneous fat thickness greater than 20 mm who have undergone emergency open abdominal surgery and sutured as routine.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Iman Aminian

Street address

Sina hospital., Hasan abad square, Imam Khomeini Ave., Tehran

City

Tehran

Province

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1136746911

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+98 21 6634 8500

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Imanaminian64@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

6th floor, Central University Organization, Ghods Ave., Keshavarz Blvd.

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Msahrai@sina.tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Iman Aminian

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

Hossein Zabihi Mahmoudabadi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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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