Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 21 8808 3689

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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
11111111111
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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6th floor, Central University Organization, Ghods Ave., Keshavarz Blvd.
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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
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
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Person responsible for updating data

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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