Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of peritoneal closure vs non-closure after non-infected elective laparotomy with midline incision

Protocol summary

Study aim
The aim of this clinical trial is to compare short term and long term affects of peritoneal closure with non-closure in an academic medical center.

Design
Two arm parallel group randomized trial, double blind,with blinded postoperative care and outcome assessment and patients, on 200 patients, using random number table for randomization.

Settings and conduct
This double blinded prospective clinical trial will be conducted in Imam Hossein Medical Center; an academic center under supervision of Shahid Beheshti University of Medical Sciences. The included participant will be randomly divided into two groups and in closure group the peritoneum will be sutured before closing the fascia layer and in non-closure group only the fascia layer will be closed at the end of surgery. the patients and the assessment team are blinded.

Participants/Inclusion and exclusion criteria
The inclusion criteria are Laparotomy with midline incision and age of equal or greater than 16. The exclusion criteria are prior history of laparotomy; diabetes mellitus; known connective tissue disorders; infection; obstetrics surgery; and emergency cases.

Intervention groups
In closure group the peritoneum will be sutured before closing the fascia layer and in non-closure group only the fascia layer will be closed at the end of surgery.

Main outcome variables
Post-op pain intensity by visual analogue scale Need for analgesic drugs Surgical wound complications Incisional hernia and adhesion assessment by physical examination after six months of surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200404046936N2**
Registration date: **2020-04-28, 1399/02/09**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-28, 1399/02/09**
Update count: **0**

Registration date
2020-04-28, 1399/02/09

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
2020-04-20, 1399/02/01

Expected recruitment end date
2020-07-21, 1399/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of peritoneal closure vs non-closure after non-infected elective laparotomy with midline incision

Public title

"Peritoneal closure in laparotomy"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Laparotomy with midline incision Age of equal or greater than 16

Exclusion criteria:

Prior history of laparotomy Diabetes mellitus Known connective tissue disorders Infection Obstetrics surgery Emergency cases

Age

From **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the random number table patients assign to the closure or non-closure groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The evaluator and patient are unaware of the group the patient is enrolled in. All patients are assessed by a resident unaware of the allotted group of the patient in regard of pain intensity, need of analgesic and wound complications and the results are filled in the checklists. Six months after the surgery a known unaware radiologist will perform an abdominal sonography and the result will be registered.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshty University of Medical Sciences

Street address

Evin, Shahid Beheshty University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2018-05-15, 1397/02/25

Ethics committee reference number

IR.SBMU.MSP.REC.1397.430

Health conditions studied

1

Description of health condition studied

peritoneum closure in laparatomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

post-op pain

Timepoint

days 1, 2 and 3 post-op

Method of measurement

visual analogue scale

2

Description

analgesic need

Timepoint

days 1, 2 and 3 post-op

Method of measurement

injection doses

3

Description

infection

Timepoint

first post-op week

Method of measurement

observation

4

Description

duration of hospitalization

Timepoint

first post-op week

Method of measurement

observation

5

Description
Bowel adhesion
Timepoint
6 months after surgery
Method of measurement
sonography device

6

Description
Incisional hernia
Timepoint
6 months after surgery
Method of measurement
Sonography device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Closure group in which the peritoneum is closed with absorbable sutures and then the abdominal fascia is closed.
Category
Treatment - Surgery

2

Description
Control group: non-closure group in which at end of surgery only the abdominal fascia layer is sutured.
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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tehran
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1617763141
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arash_mtofigh@yahoo.com
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
Street address
Evin
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 23871
Email
info@sbmu.ac.ir
Web page address
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
Arash Mohammadi Tofigh
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
General Surgery
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Person responsible for updating data

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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
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