Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of Prophylactic Retention Suture in Preventing Dehisence in Midline Laparotomy in High Risk Patient in Dr. Shariati Hospital in 2008-2010

Protocol summary

Summary

The objective of the present study is to assess the prophylactic retension suture in preventing dehiscince in midline laparotomy in high risk patient. In this study, 300 patients in two academic centers, who need midline laparotomy and are high risk for dehiscence, are randomly assigned into two groups. In one group, the fascia is closed routinely and in the other group, we use retention suture additionally. Wound healing, dehiscence and evisceration are mainly compared between the two groups. Need for reoperation, postoperative admission duration, postoperative pain, wound infection, and late incisonal hernia is also assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105082982N3**
Registration date: **2011-07-21, 1390/04/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-07-21, 1390/04/30

Registrant information

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Zhamak Khorgami
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Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2008-08-22, 1387/06/01

Expected recruitment end date

2010-03-21, 1389/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of Prophylactic Retention Suture in Preventing Dehisence in Midline Laparotomy in High Risk Patient in Dr. Shariati Hospital in 2008-2010

Public title

Assessment of Prophylactic Retention Suture in Preventing Dehiscence in Midline Laparotomy in High Risk Patient

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: undergoing midline laparotomy, being high risk for dehiscence or any other risk factors, informed consent for enrolling in the study, incision more than 10 cm Exclusion criteria: age under 18, no informed consent, incision length for less than 10 cm

Age

No age limit

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **300**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences
Street address
Central building, Qhods avenue
City
Tehran
Postal code
Approval date
2011-01-12, 1389/10/22
Ethics committee reference number
89/130/1278/ه

Health conditions studied

1

Description of health condition studied
Dehiscence
ICD-10 code
T81.3
ICD-10 code description
Disruption of operation wound, not elsewhere classified

Primary outcomes

1

Description
Wound Dehiscence
Timepoint
Daily
Method of measurement
Clinical Examination

Secondary outcomes

1

Description
Wound Infection
Timepoint
Daily
Method of measurement
Clinical Examination

2

Description
Postoperative hospital stay
Timepoint
while discharge
Method of measurement
Based on hospital record

3

Description
Postoperative pain
Timepoint
Daily
Method of measurement
Visual analogue score

4

Description
Incisional Hernia
Timepoint
each 2 months till 6 month
Method of measurement
Clinical Examination

5

Description
Evisceration
Timepoint
Daily
Method of measurement
Clinical Examination

6

Description
Reoperation due to wound dehiscence
Timepoint
until 30 days postoperative
Method of measurement
Based on hospital record

7

Description
Mortality due to dehiscence
Timepoint
until 30 days postoperative
Method of measurement

Based on hospital record

Intervention groups

1

Description
In control group, the fascia was sutured using a 0-1 nylon loop string continuously, 1 cm from edge of linea alba. Gigyli tie is applied each 5 cm. Fascia is closed with at least two thread from each side and are tied in the center. Subcutaneous tissue is not sutured and skin is closed using 3-0 nylone in separate way.
Category
Treatment - Surgery

2

Description
In intervention group, the fascia is sutured by the same technique in control group while retention suture is added by using a 0-1 nylon string each 10 cm containing all the skins, subcutaneous tissue, rectus sheath out of peritoneum, with a 5 cm distances left from each ends of the incision.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Shariati Hospital
Full name of responsible person
Dr. Zhamak Khorgami
Street address
Shariati Hospital, North Kargar Avenue,
City
Tehran

2

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Dr. Ali Aminian
Street address
Keshavarz Blvd
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Shahin Akhonzade
Street address
Research deputy, Faculty of Medicine, Poursina Avenue, Keshavarz Blvd
City
Tehran
Grant name
در قالب بودجه پایان نامه دستیار تخصصی
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
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Zhamak Khorgami
Position
General Surgeon/ faculty of surgery department
Other areas of specialty/work
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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty