

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### Comparison between simple suture and continuous suture in fascia closure in midline laparotomy

#### Protocol summary

##### Study aim

Laparotomy is meaning to incision in The abdominal wall area for access to the abdominal cavity is performed in a variety of surgical procedures. Abdominal wall herniation, infection, rupture of the wound (ulceration or muscle layers) and chronic drainage are potential complications of using this procedure. These complications are influenced by various factors. Various articles have compared some of the causes, including absorbable sutures, non-absorbable sutures by monofilaments, multifilament interlocking sutures, and low-absorption sutures (those with 30 days elongation strength). High-uptake sutures (those that lose their tensile strength over a period of 30 days) are referred to as contributors to the modulation of laparotomy complications. Since the suture type is fully controlled by the surgeon, the aim of this study was to compare Simplel and Continius suture in occlusion of fascia in incision midline laparotomy for incisional herniation, wound dehiscence, postoperative pain.

##### Design

Patients are randomly divided into two treatment groups using Simplex Suture for Reconstruction of Fascia and Suture Contius by matching age and sex variables.

##### Settings and conduct

In this clinical trial study patients undergoing elective laparotomy in 2019 and 2020 will be enrolled in this study.

##### Participants/Inclusion and exclusion criteria

In this clinical trial study patients with elective laparotomy will be included in the study. Exclusion criteria included previous abdominal surgery, malignancies, eating disorders, diabetes, ascites, high intra-abdominal pressure, disability, and lack of satisfaction with the study.

##### Intervention groups

Treated with Simplel suture for repair of fascia and suture cont

##### Main outcome variables

incidence of fascia dehiscence

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160803029181N9**

Registration date: **2019-12-10, 1398/09/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-12-10, 1398/09/19**

Update count: **0**

##### Registration date

2019-12-10, 1398/09/19

##### Registrant information

##### Name

Nasser Malekpour Alamdari

##### Name of organization / entity

Shaid Behesht University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2207 4089

##### Email address

nassermalekpour@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-22, 1398/09/01

##### Expected recruitment end date

2020-11-21, 1399/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison between simple suture and continuous suture in fascia closure in midline laparotomy

**Public title**

simple suture versus continuous suture in fascia closure

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients who needed Elective Laparotomy, will enroll

**Exclusion criteria:**

Exclusion criteria included previous abdominal surgery, malignancies, eating disorders, diabetes, ascites, high intra-abdominal pressure, disability, and lack of satisfaction with the study.

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

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

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients are randomly divided into two treatment groups using Simplex suture to repair fascia and suture continuous by matching age and sex variables.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients and analyzers are blind to the study

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics commity of Shahid Beheshti University of Medicasl Sciences

**Street address**

Daneshju Avenue Velenjak

**City**

tehran

**Province**

Tehran

**Postal code**

1985717443

**Approval date**

2019-11-05, 1398/08/14

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1398.385

**Health conditions studied****1****Description of health condition studied**

ELECTIVE LAPARATOMY

**ICD-10 code**

Y84

**ICD-10 code description**

Other medical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

**Primary outcomes****1****Description**

fascial dehiscence

**Timepoint**

3,6,12 month after surgery

**Method of measurement**

sonography

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group1:Treated with Simple Suture for fascia repair:

**Category**

Treatment - Surgery

**2****Description**

Intervention group 2: Treated with continuous suture

**Category**

Treatment - Surgery

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Modarres Hospital

**Full name of responsible person**

Nasser Malekpour

**Street address**

Modarres Hospital;Kaj Sq;Saadat Abad;

**City**

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**Province**

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### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Seyyed Ali Ziai

**Street address**

Danshju Ave Velenjak

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aliziai@sbmu.ac.ir

**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**

Nasser Malekpour Alamdari

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

General Surgery

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## Person responsible for scientific inquiries

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**Other areas of specialty/work**

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## Person responsible for updating data

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Associate professor  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

No more information

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available