

# 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 analyst
- 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 laparotomy

#### 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.

##### City

tehran

##### Province

Tehran

##### Postal code

1617763141

##### Phone

+98 21 7758 5851

##### Email

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

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##### 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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Shahid Madani st.

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## Person responsible for scientific 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

### 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  
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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