

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Therapeutic outcomes of mesh fixation with suture versus glue in inguinal hernia repair with Lichtenstein method

#### Protocol summary

##### Study aim

Therapeutic outcomes of mesh fixation with suture versus glue in inguinal hernia repair with Lichtenstein method.

##### Design

Two arm parallel group randomised controlled trial, with blinded patients. 40 patients enter the study. Random number table is used for randomization.

##### Settings and conduct

Forty patients with indirect inguinal hernia who are candidate for Lichtenstein hernioplasty at Imam Hossein Medical Center, Tehran, will enter this randomised controlled, single blind study. Patients will be randomly placed in one of two groups; mesh fixation with N-Hexyl Cyanoacrylate glue group or suture group. Patients are not aware about their group and are blinded. They will be followed up for for 1 year and data will be collected and will be compared.

##### Participants/Inclusion and exclusion criteria

Patients candidate for indirect inguinal hernioplasty will be included in the study. Exclusion criteria are impossible to follow patients, recurrent hernia, long time use of anti-inflammatory drugs, physical status classification grade 3 and higher according to ASA grading system, addiction to alcohol, drug and opium.

##### Intervention groups

In Group 1 N-Hexyl cyanoacrylate glue will be used for mesh fixation. In Group 2 or control group suture will be used for mesh fixation.

##### Main outcome variables

Operation time; post-op pain; chronic pain ; post-op infection; hematoma; seroma; hospital stay; recurrence; urinary problems.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200404046936N3**

Registration date: **2020-05-18, 1399/02/29**

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

Last update: **2020-05-18, 1399/02/29**

Update count: **0**

##### Registration date

2020-05-18, 1399/02/29

##### 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

2020-05-04, 1399/02/15

##### Expected recruitment end date

2020-07-20, 1399/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Therapeutic outcomes of mesh fixation with suture versus glue in inguinal hernia repair with Lichtenstein method

##### Public title

"Mesh fixation with glue in hernia repair"

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with indirect inguinal hernia

### Exclusion criteria:

Impossible to follow Recurrent hernia Long time use of anti-inflammatory drugs ASA physical status classification 3 and higher Addiction to alcohol,drugs,opium

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: 40

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization is done using a random number table. A mixture of numbers from 1 to 40 is made, and patients entering the study get the next code from the table in order. If the number is below 20 the patient will be assigned to the intervention group, and If it is above 20, he or she will be assigned to the control group. Patients in the control group will be operated with suture and the intervention group with glue.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The patient is unaware that he or she is in the glue or suture group.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

##### Street address

Evin, Shahid Beheshti 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.1397.276

## Health conditions studied

### 1

#### Description of health condition studied

Comparing mesh fixation with suture versus glue in Lichtenstein inguinal hernia repair

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

1st, 8th, 24th hour post op then 1 week and 1,3,6,12 months after.

#### Method of measurement

numeric rating scale(NRS) to assess pain.the patients rate their pain on a defined faces pain rating scale.for example, 0-10 where 0 is no pain and 10 is the worst pain imaginable.

### 2

#### Description

Recurrence

#### Timepoint

1week-1,3,6,12 months after surgery.

#### Method of measurement

Physical examination

### 3

#### Description

Infection

#### Timepoint

1 day-1 week-1 month after surgery

#### Method of measurement

Observation and physical exam

### 4

#### Description

Duration of surgery

#### Timepoint

Start to the end of anesthesia in the operating room

#### Method of measurement

Anesthesia sheet time table

## 5

### **Description**

Duration of hospitalization

### **Timepoint**

Days in hospital from the end of surgery

### **Method of measurement**

The patients file

## 6

### **Description**

Hematoma

### **Timepoint**

8 hours-1 day-1 week after the surgery

### **Method of measurement**

Physical examination

## 7

### **Description**

Seroma formation

### **Timepoint**

8 hours-1 day-1 week after the surgery

### **Method of measurement**

Physical examination

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: patients with indirect inguinal hernia candidate for Lichtenstein hernioplasty with mesh fixation with cyanoacrylate glue

#### **Category**

Treatment - Surgery

### 2

#### **Description**

Control group: patients with indirect inguinal hernia candidate for Lichtenstein hernioplasty with mesh fixation with suture

#### **Category**

Treatment - Surgery

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Emam Hossein Medical Center

##### **Full name of responsible person**

Arash Mohammadi Tofigh

##### **Street address**

Emam Hossein Medical Center, Shahid Madani st.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1617763141

##### **Phone**

+98 21 7343 0000

##### **Email**

arash\_mtofigh@yahoo.com

## **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**

milad karimian ghadim

##### **Position**

resident

##### **Latest degree**

Medical doctor

**Other areas of specialty/work**

General Surgery

**Street address**

no. 3, motahari alley,bahonar ave.,niavaran

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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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arash\_mtofigh@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

milad karimian ghadim

**Position**

resident

**Latest degree****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 after concealment of the identities.

**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**