

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)

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+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.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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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

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