

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation of using fibrin glue in Mesh Fixation in comparison with suture fixation for inguinal Hernia repairment by Liechtenstein method to reduce complication

Protocol summary

Study aim

Evaluation of using fibrin glue in Mesh Fixation in comparison with suture fixation to reduce complication in inguinal Hernia repairment by Liechtenstein method

Design

120 patients with inguinal hernia entered this single blinded clinical trial from August 2018 and followed until six month. After examining the patients considering the inclusion and exclusion criteria, 20 patients were excluded. The remaining 100 patients were randomly divided into two groups of 50. The mesh was fixed by fibrin glue in first group, and by suture in another group .

Settings and conduct

This single blind clinical trial study was performed on patients with inguinal hernia referred to Shahid Beheshti and Ayatollah Rouhani hospitals in Babol. In this study, the analyzer was not informed about the method of mesh fixing, and the way that data was encoded.

Participants/Inclusion and exclusion criteria

patients aged 18 to 80 years old, unilateral or bilateral inguinal hernia, and patients with Liechtenstein Hernioplasty included in this study. patients excluded if they have known femoral hernia, large scrotal hernia, emergency operation for strangulated hernia, recurrent hernia, allergy to Bovin Aprotinin, and if they refused to be part of this study.

Intervention groups

All patients underwent Lichtenstein hernioplasty. The mesh was fixed by fibrin glue in Intervention group, and in the control group by suture.

Main outcome variables

Pain; recurrence of inguinal hernia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171213037857N3**

Registration date: **2019-04-25, 1398/02/05**

Registration timing: **retrospective**

Last update: **2019-04-25, 1398/02/05**

Update count: **0**

Registration date

2019-04-25, 1398/02/05

Registrant information

Name

Ali Zahedian Tijeneki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3225 6285

Email address

a.zahedian@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

2017-08-23, 1396/06/01

Actual recruitment end date

2019-02-20, 1397/12/01

Trial completion date

2019-02-20, 1397/12/01

Scientific title

Evaluation of using fibrin glue in Mesh Fixation in comparison with suture fixation for inguinal Hernia

repairment by Liechtenstein method to reduce complication

Public title

result of mesh fixation methods in groin hernia repairment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients aged 18 to 80 years unilateral or bilateral inguinal hernia patients with Liechtenstein Hernioplasty

Exclusion criteria:

known femoral hernia large scrotal hernia emergency operation for strangulated hernia recurrent hernia allergy to Bovin Aprotinin patient refusal

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

4

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study patients were randomly divided into two groups of 50 individuals by simple random allocation using the table of random numbers.

Blinding (investigator's opinion)

Single blinded

Blinding description

Person who examine the outcomes of patients was not aware of type of the surgery and the grouping of patients and only received the patients' names. The analyzer also received encoded data and did not know how patients were grouped.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Ganjafrooz Street, Babol University of Medical Sciences

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Approval date

2018-06-10, 1397/03/20

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.097

Health conditions studied

1

Description of health condition studied

inguinal hernia

ICD-10 code

K40

ICD-10 code description

Inguinal hernia

Primary outcomes

1

Description

Pain

Timepoint

Patient pain assessment was performed 7 days, one month and 6 months after Herniorrhaphy surgery.

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Recurrence of inguinal hernia

Timepoint

Evaluation of inguinal hernia recurrences was performed one month and 6 months after Herniorrhaphy surgery

Method of measurement

clinical examination

Intervention groups

1

Description

Intervention group: mesh fixation with fibrin glue in inguinal hernia repairment

Category

Treatment - Surgery

2

Description

Control group: mesh fixation with suture in inguinal hernia repairment

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti and Ayatollah Rohani Hospitals in Babol

Full name of responsible person

Ali Zahedian Tajenaki

Street address

Ganjafrooz Street, Babol University of Medical Sciences

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Phone

+98 11 3219 9592

Email

a.zahedian@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Ali Zahedian Tajenaki

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Vice-Chancellor for Research, School of Medicine, Babol 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

Babol University of Medical Sciences

Full name of responsible person

Ali Zahedian Tajenaki

Position

Assistant Professor in Department of Surgery

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

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Babol University of Medical Sciences

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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

In this study, all clinical and demographic data are encoded in SPSS software for sharing.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Doctors and people working in academic institutions related to medical sciences

Under which criteria data/document could be used

Use of this research data will be permitted in meta-analysis studies

From where data/document is obtainable

Contact: Alizahed20@yahoo.com, to receive the data

What processes are involved for a request to access data/document

The applicant will be contacted within 48 hours, and if the academic and employment records of the research environment are properly submitted, research data will be provided to the applicant upon confirmation of the identity of the originator.

Comments