Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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 repairement
Category
Treatment - Surgery

2

Description

Control group: mesh fixation with suture in inguinal hernia repairement

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

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Sponsors / Funding sources

1

Sponsor

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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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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