

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of the effect of inguinal hernia repair with Liechtenstein method with progrip mesh compared to prolene mesh in reducing complications

Protocol summary

2018-05-02, 1397/02/12

Study aim

Comparison of the effect of inguinal hernia repair using the progrip mesh on improving the quality of life relative to the prolene mesh and their complications

Design

Two arm parallel group randomised trial.

Settings and conduct

In this study, patients were randomly divided into two groups of 40, based on their inclusion criteria. The first group with progrip mesh and the second group with prolene mesh at the Ayatullah Rohani Babylon Medical Center are going under the hernia repair surgery. The amount of pain is assessed based on the visual scale (VAS) postoperation as well as on possible complications.

Participants/Inclusion and exclusion criteria

inclusion criteria: Unilaterla inguinal hernia, age over 18 years old exclusion criteria: recurrence, bilateral, incarcerated inguinal hernia and femoral hernia

Intervention groups

40 patients as progrip mesh group 40 patients , as prolene mesh group

Main outcome variables

Postoperation pain; postoperation complications (hematoma, infection, urinary retention); life style

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171213037857N1**

Registration date: **2018-05-02, 1397/02/12**

Registration timing: **retrospective**

Last update: **2018-05-02, 1397/02/12**

Update count: **0**

Registration date

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

2017-08-23, 1396/06/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of inguinal hernia repair with Liechtenstein method with progrip mesh compared to prolene mesh in reducing complications

Public title

Comparison of surgical complications of inguinal hernia repair using two mesh types

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

unilateral inguinal hernia age over 18 years old

Exclusion criteria:

recurrent inguinal hernia bilateral inguinal hernia
incarcerated inguinal hernia femoral hernia

Age

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

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

no

Blinding (investigator's opinion)

Not blinded

Blinding description

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 science

Street address

Ganj Afrouz St. Babol University of medical science

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Approval date

2017-01-04, 1395/10/15

Ethics committee reference number

MUBABOL.REC.1395.197

Health conditions studied

1

Description of health condition studied

post operative pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

postoperative pain

Timepoint

4 and 8 to 12 hours postoperation

Method of measurement

visual analog scale(VAS)

2

Description

postoperative hematoma

Timepoint

12 and 24 hours postoperation

Method of measurement

physical examination

3

Description

Surgery Site Infection

Timepoint

7 days postoperation

Method of measurement

physical examination

4

Description

postoperation urinary retention

Timepoint

12 to 24 hours postoperation

Method of measurement

interview and physical examination

5

Description

lifestyle

Timepoint

6-12 hours and 24 hours post operation and 6 months later

Method of measurement

EQ-5D-EL health question form

Secondary outcomes

empty

Intervention groups

1

Description

40 people as a Liechtenstein-treated group with progrid mesh

Category

Treatment - Surgery

2

Description

Control group: 40 people as a Liechtenstein-based and prolene-operated surgical group

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani educaional medical center- Babol

Full name of responsible person

Ali zahedian Tijanki

Street address

Ganj Afrouz St.

City

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3223 8262

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

Reza Ghadimi

Street address

Babol University of Medical Science, Ganjafrouz St.

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Phone

+98 11 3219 0558

Email

rezaghadimi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Amin Gorjizadeh

Position

General Surgery Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Surgery Department, Shahid Beheshti Hospital, Shahid Sargord Ghaemi St. Babol

City

Babol

Province

Mazandaran

Postal code

4716681451

Phone

+98 11 3225 6005

Email

agorjizadeh@hotmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Ali Zahedian Tijeneki

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Babol University of Medical Sciences, Ganj Afrooz Avenue, Babol, Mazandaran.

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Phone

+98 11 3225 6285

Fax

Email

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Amin Gorjizadeh

Position

General Surgery Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Surgery Department, Shahid Beheshti Hospital,
Shahid Sargord Ghaemi St. Babol

City

Babol

Province

Mazandaran

Postal code

4716681451

Phone

+98 11 3225 6005

Email

agorjizadeh@hotmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Title and more details about the data/document

part of the information

When the data will become available and for how long

one year after publish

To whom data/document is available

researchers

Under which criteria data/document could be used

no more information

From where data/document is obtainable

agorjizadeh@hotmail.com Surgery Department, Shahid Beheshti Hospital, Shahid Sargord Ghasemi St. Babol. 4716681451

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

sending the request by email or mail evaluation and respond

Comments