

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of Early Complications and Recurrence in Inguinal Hernia Surgery with Laparoscopic (TAPP) and Open Methods (Lichtenstein)

Protocol summary

Pain; Infection; Hematoma; Seroma; Recurrence

Study aim

Comparison of Lichtenstein Open Hernia Repair with TransAbdominal PrePeritoneal Laparoscopic Repair (both with Spinal Anesthesia) for Early and Late Complications (e.g; Post-operative Pain, Infection, Hematoma, Seroma and Recurrence within the First Year)

Design

Two Arm Parallel Group Randomized Clinical Trial of 84 Patients, Randomization by R Software

Settings and conduct

Eligible patients were randomized into two open and laparoscopic groups. Hernia repair was done with BARD prolene meshes. Spinal anesthesia was done with 15mg bupivacaine in both groups. Laparoscopic group received mild intravenous sedation with 1mg midazolam, 100mg fentanyl and 130mg/h propofol infusion in order to tolerate insufflation. Post-op pain was evaluated by Visual Analog Scale. Zero score was given for Painlessness and 10 score was given for the worst pain the patient had ever experienced. All patients received 500mg acetaminophen and maximum 3 doses of morphine sulfate and pain evaluation was done before narcotic injection. 48 hours and a week after discharge patients were examined for pain and early post-operative complications. Recurrence was evaluated in 6 and 12 months by physical examination.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Unilateral Primary Inguinal Hernia in Patients older than 18 Years of Age Exclusion Criteria: Patient Dissent; Recurrent Hernia; Bilateral Hernia, Patients with Underlying Diseases (e.g; Asthma, Benign prostatic hyperplasia, Chronic obstructive pulmonary disease) and Heavy Workers

Intervention groups

Patients with inguinal hernia will be operated via either of the well-known laparoscopic transabdominal preperitoneal (first group) or open Lichtenstein (second group) methods.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200727048228N1**

Registration date: **2020-09-05, 1399/06/15**

Registration timing: **retrospective**

Last update: **2020-09-05, 1399/06/15**

Update count: **0**

Registration date

2020-09-05, 1399/06/15

Registrant information

Name

Mansour Nateghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8819 2231

Email address

mansournateghi@sbbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-25, 1397/06/03

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

2018-08-25, 1397/06/03

Actual recruitment end date

2019-02-19, 1397/11/30

Trial completion date

2020-02-19, 1398/11/30

Scientific title

Comparison of Early Complications and Recurrence in Inguinal Hernia Surgery with Laparoscopic (TAPP) and Open Methods (Lichtenstein)

Public title

Comparison of Inguinal Hernia Repair with Laparoscopic and open Methods

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Consent of the Patients Unilateral Non-Incarcerated Primary Inguinal Hernia (Non-Recurrent)

Exclusion criteria:

Patient Dissent Recurrent Hernia Bilateral Hernia Patients with Underlying Diseases (e.g; Asthma, Benign prostatic hyperplasia, Chronic obstructive pulmonary disease) Heavy Workers

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Actual sample size reached: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted Block Randomization, Block Size of 2 An 84 row random sequence was produced by R software, then patients who consent to either type of surgery where registered into the aforementioned sequence according to the order of referral and patient's surgery type was determined.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

As most laparoscopic surgeries are performed under general anesthesia, in order to make both study arms equal, both arms will undergo operation with spinal anesthesia

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of School of Medicine - Shahid Beheshti University of Medical Sciences

Street address

Faculty of Medicine, Shahid Beheshti University of Medical Sciences, Arabi St., Yaman St., Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2018-07-10, 1397/04/19

Ethics committee reference number

IR.SBMU.MSP.REC.1397.480

Health conditions studied

1

Description of health condition studied

Inguinal Hernia

ICD-10 code

K40.90

ICD-10 code description

Unilateral inguinal hernia, without obstruction or gangrene, not specified as recurrent

Primary outcomes

1

Description

Severity of Post-op Pain

Timepoint

Just After Surgery, 8h, 24h, 48h and a week after the operation

Method of measurement

Visual Analogue Scale

2

Description

Surgical Site Infection

Timepoint

2 and 7 days after surgery

Method of measurement

Physical Examination

3

Description

Seroma

Timepoint

2 and 7 days after surgery

Method of measurement

Physical Examination

4

Description

Hematoma

Timepoint

2 and 7 days after surgery

Method of measurement

Physical Examination

5

Description

Recurrence

Timepoint

6 months and a year after surgery

Method of measurement

Physical Examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Trans Abdominal PrePeritoneal Laparoscopic Surgery with Spinal Anesthesia (standard 3 port surgery with transabdominal peritoneal dissection and fixation of mesh in preperitoneal space)

Category

Treatment - Surgery

2

Description

Control group: Lichtenstein Open Surgery with Spinal Anesthesia with standard inguinal incision, incising external oblique fascia, skeletonizing cord, resection of hernia sac and fixation of mesh

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center**Name of recruitment center**

Imam Hussein Hospital

Full name of responsible person

Alireza Manafi

Street address

Imam Hussein Hospital, Madani St, Nezam-Abad

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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

Research Chancel of 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

Mansour Nateghi

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Behzad Nemati Honar

Position

Associate Professor

Latest degree

Subspecialist

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

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information about the main outcome may be shared

When the data will become available and for how long

Accessible after publication of the trial

To whom data/document is available

Researchers and employees in academic and scientific institutions

Under which criteria data/document could be used

Use of data to complete their studies

From where data/document is obtainable

Dr. Mansour Nateghi

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

Data can be shared after reviewing the researcher's request and provision of sufficient documentation of his/her research and the reason for using the data

Comments