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

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

Pain; Infection; Hematoma; Seroma; Recurrence

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@sbmu.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
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Sponsors / Funding sources

1

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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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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