

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

**City**

Tehran

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**Postal code**

1617763141

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+98 21 7343 0000

**Email**

info@ehmc.ir

**Web page address**

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### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi

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**Web page address**

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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**

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**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

General Surgery

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**Email**

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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**