

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### comparative study of surgical results of laparoscopic hernia surgery using TEP method with and without TACKER

#### Protocol summary

##### Study aim

Evaluation of inguinal hernia recurrence in TEP Procedure with and without takers

##### Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment 54 patients

##### Settings and conduct

This randomized clinical trial was conducted during 2018-2019 in Alzahra and Kashani hospitals in Isfahan. Three takers are used in Totally Extraperitoneal Procedure (TEP). One 10 mm sub-umbilical and two five-millimeter takers, one above the symphysis and the other in the middle of the umbilical distance and , and then the separation of pre-peritoneal space by balloon, laparoscopy and Or CO2 gas, after releasing the sac hernia and fixing it, the mesh enters the peritoneal space and is fixed by various techniques such as stitching, using Taker or using Fibrin glue.

##### Participants/Inclusion and exclusion criteria

patients over 18 years old were entered the study with hernia inguinal. patients with associated medical problems who have general anesthesia or elective surgery and • Patients with symptoms of peritonitis, intestinal obstruction or intestinal perforation. • Local or dissemination infection (urinary tract infection, skin, sepsis and lungs) • Patients with chronic mental illness • Patients with scrotal hernia • Predisposing factors of recurrence of hernia such as intra-abdominal pressure enhancing factors such as COPD, excessive obesity (BMI<sup>2</sup> >35 kg/m<sup>2</sup>), chronic cough, pregnancy were not entered in the study.

##### Intervention groups

Patients over 18 years of age with inguinal hernia

##### Main outcome variables

In this study, the variables of recurrence of hernia, infection, postoperative bleeding, postoperative pain, duration of hospitalization, time required to return to daily activities, hematoma after surgery, postoperative neuroalgia, were investigated.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201123049471N1**

Registration date: **2020-11-28, 1399/09/08**

Registration timing: **retrospective**

Last update: **2020-11-28, 1399/09/08**

Update count: **0**

##### Registration date

2020-11-28, 1399/09/08

##### Registrant information

##### Name

Amirhosein Karimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3824 2095

##### Email address

amirhosein84p@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-01, 1397/04/10

##### Expected recruitment end date

2019-07-01, 1398/04/10

##### Actual recruitment start date

2018-09-21, 1397/06/30

##### Actual recruitment end date

2019-09-11, 1398/06/20

##### Trial completion date

2020-05-14, 1399/02/25

##### Scientific title

comparative study of surgical results of laparoscopic hernia surgery using TEP method with and without TACKER

#### Public title

Evaluation of fixation in inguinal hernia surgery by TEP method

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients over 18 years old with inguinal hernia

##### Exclusion criteria:

Associated medical problems that had contraindicated general anesthesia or elective surgery. Patients with symptoms of peritonitis, intestinal obstruction or intestinal perforation Local or dissemination infection (urinary tract infection, skin, sepsis and lungs) Patients with chronic mental illness • Patients with scrotal hernia Predisposing factors for recurrence of hernia such as intra-abdominal pressure enhancing factors such as COPD, excessive obesity (BMI<sup>2</sup> 35 kg/m<sup>2</sup>), chronic cough, pregnancy

#### Age

From **18 years** old to **75 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant
- Investigator

#### Sample size

Target sample size: **50**

Actual sample size reached: **54**

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

In this study, the surgeon determines the type of fixation and does not have blinding compared to the study. The questionnaires were completed after surgery and 6 months after surgery and at the end of the study, the type of fixation was determined from the patient's surgeon and analyzed accordingly.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

#### Ethics committees

#### 1

#### Ethics committee

##### Name of ethics committee

•Ethics committee of Isfahan University of Medical Sciences

##### Street address

Hezarjarib St., Isfahan University of Medical Sciences

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2019-07-01, 1398/04/10

#### Ethics committee reference number

IR.MUI.MED.REC.1398.178

#### 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

Hernia Recurrence Check

#### Timepoint

After surgery and 4 weeks after surgery and 6 months after surgery

#### Method of measurement

Check inguinal hernia recurrence by examination

#### Secondary outcomes

empty

#### Intervention groups

#### 1

#### Description

Intervention group 1: In patients undergoing surgery after sac hernia release and its reduction, the mesh enters the pre-peritoneal space and is proved by various techniques such as sutures, use of Taker or fibrin glue. fixation is not performed.

#### Category

Treatment - Surgery

#### 2

#### Description

Intervention group2: In patients undergoing surgery after release of sac hernia and its reduction, the mesh enters the pre-peritoneal space and

**Category**

Treatment - Surgery

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Kashani and Alzahra Hospitals, Isfahan University of Medical Sciences

**Full name of responsible person**

Amirhosein Karimi

**Street address**

No. 7, 8th Side St., Atlasi St., Timsar Fallahi Ave., Safaiyeh, yazd, Iran

**City**

yazd

**Province**

Yazd

**Postal code**

8916853855

**Phone**

+98 35 3824 2095

**Email**

amirhosein84p@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr. Shaghayegh Haghjoo Javanmard

**Street address**

Hezarjarib Street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

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**Phone**

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**Email**

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**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Esfahan University of Medical Sciences

**Proportion provided by this source**

30

**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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Amirhosein Karimi

**Position**

General surgery resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Surgery

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**Contact**

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## Person responsible for updating data

### Contact

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Esfahan University of Medical Sciences

**Full name of responsible person**

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## 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**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available