Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

comparative study of surgical results of laparascopic 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 symphesis and the other in the middle of the umbilical distance and , and then the separation of pre-peritonal space by balloon, laparoscopy and Or CO2 gas, after releasing the sac hernia and fixing it, the mesh enters the peritonal 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 dessemination 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˃35 kg/m2), 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 laparascopic 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 contrandected 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 (BMIˀ35 kg/m2), 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
Isfehan
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-peritonal 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-peritonal 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

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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

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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 reident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Contact

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

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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