Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of recurrence and postoperative complications between open and laparoscopic surgical procedures ventral hernia repair

Protocol summary

Study aim
Comparison of recurrence and postoperative complications between open and laparoscopic surgical procedures ventral hernia repair

Design
This study will be conducted as a randomized, double-blind clinical trial.

Settings and conduct
This study is about comparison of recurrence and postoperative complications between open and laparoscopic surgical procedures ventral hernia repair in Imam Khomeini Hospital in Kermanshah. In this study, the patients and the peoples who measuring the variables would be unaware of the presence of patients in the first group and or in the second groups. Only the surgeon aware about grouping.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Ages between 18 and 65 years old - Have ventral hernia surgery by laparoscopic and open method Exit criteria : Emergency hernia - Factors that increase intra-abdominal pressure, such as COPD, too much obesity, BPH and pregnancy

Intervention groups
Intervention: Surgical type Intervention group1: Surgical patients with laparoscopic surgery Intervention group2: Surgical patients with open surgery

Main outcome variables
Infection, hematoma, skin necrosis and seroma caused by laparoscopy and open surgery Duration of hospitalization after laparoscopic and open surgery Time to feel pain after laparoscopy and open surgery Time to return to work after laparoscopic and open surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100609004141N4**
Registration date: **2019-07-18, 1398/04/27**
Registration timing: **prospective**

Last update: **2019-07-18, 1398/04/27**
Update count: **0**

Registration date
2019-07-18, 1398/04/27

Registrant information

Name
ezatollah sadeghi

Name of organization / entity
kermanshah university of medical sciences

Country
Iran (Islamic Republic of)

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+98 83 1427 6325

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dr.makhsosy@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01

Expected recruitment end date
2019-11-21, 1398/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of recurrence and postoperative complications between open and laparoscopic surgical procedures ventral hernia repair

Public title

Comparison of recurrence and postoperative complications between open and laparoscopic surgical procedures ventral hernia repair

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ages between 18 and 65 years old Have ventral hernia surgery by laparoscopic method Have ventral hernia surgery by open method

Exclusion criteria:

Emergency hernia Factors that increase intra-abdominal pressure, such as COPD Too much obesity BPH Pregnancy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The assignment of patients to each group will be applied based on randomization block to control the effect of age and sex. And so on the proportion of sex (women and men) and age (under 40, 40 years old and more) will be approximately the same in the two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patients and the peoples how measuring the variables would be unaware of the presence of patients in the first group and or in the second groups. Only the surgeon aware about grouping, after of ending the evoluation of necessary variables, groups of each person will be spesified in cheklist, based on coding system.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Deputy of Research and Technology, Building No. 2, Shahid Beheshti Blvd., Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2019-04-24, 1398/02/04

Ethics committee reference number

IR.KUMS.REC.1398.122

Health conditions studied

1

Description of health condition studied

Ventral hernia

ICD-10 code

K43.9

ICD-10 code description

Ventral hernia without obstruction or gangrene

Primary outcomes

1

Description

Infection caused by laparoscopy and open surgery

Timepoint

1: 6 weeks after surgery 2: 6 ± 15 months after surgery

Method of measurement

By observing the patient

2

Description

Hematoma caused by laparoscopy and open surgery

Timepoint

1: 6 weeks after surgery 2: 6 ± 15 months after surgery

Method of measurement

By observing the patient

3

Description

Skin necrosis caused by laparoscopy and open surgery

Timepoint

1: 6 weeks after surgery 2: 6 ± 15 months after surgery

Method of measurement

By observing the patient

4

Description

Seroma caused by laparoscopy and open surgery

Timepoint

1: 6 weeks after surgery 2: 6 ± 15 months after surgery

Method of measurement

By observing the patient

5

Description

Duration of hospitalization after laparoscopic and open surgery

Timepoint

After surgery until discharge

Method of measurement

Duration of patient admission in hours, in hospital after surgery

6

Description

Time to feel pain after laparoscopy and open surgery

Timepoint

Immediately after surgery

Method of measurement

The number of minutes someone has pain after the surgery

7

Description

Time to return to work after laparoscopic and open surgery

Timepoint

Immediately after surgery

Method of measurement

The number of hours that a person will need to return to his head after surgery.

Secondary outcomes

empty

Intervention groups

1

Description

The intervention is the type of surgery. Intervention group1: Patients who are eligible for inclusion in the study are included in the study and without knowing , they are undergoing laparoscopic surgery. Laparoscopic surgery is a type of surgery in which, a thin, luminous tube is placed inside a cut in the abdomen or pelvis so that the surgeon can see the patient's part without breaking the member and then heal it.

Category

Treatment - Surgery

2

Description

The intervention is the type of surgery. Intervention group2: Patients who are eligible for inclusion in the study are included in the study and without knowing , they are undergoing open surgery. Open surgery is a type of surgical procedure in which the skin and muscles are completely cracked and opened so that the surgeon can see the patient's part with the eye and then heal it.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital in Kermanshah

Full name of responsible person

Dr Behnam Reza Makhsosy

Street address

Imam Khomeini Hospital in Kermanshah, Naghliye avenue, Kermanshah

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6718743161

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ihosp@kums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Farid Najafi

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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

Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Dr Behnam Reza Makhsosy
Position
Surgeon of Imam Khomeini Hospital in Kermanshah
Latest degree
Specialist
Other areas of specialty/work
General Surgery
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Person responsible for scientific inquiries

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Surgeon of Imam Khomeini Hospital in Kermanshah
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Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Sharmin Rahmani
Position
Researcher of Research Unit, Imam Khomeini Hospital, Kermanshah
Latest degree
Master
Other areas of specialty/work
Biostatistics
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sh.rahmani90@yahoo.com

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
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
After the samples being unidentifiable, data is publishable .
When the data will become available and for how long
The access period; Starts 6 months after publishing the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
People who try to help science can use data.
From where data/document is obtainable
Expert of Research Unit of Imam Khomeini Hospital in Kermanshah , Sharman Rahmani , sh.rahmani90@yahoo.com
What processes are involved for a request to access data/document

1- Send a request to sh.rahmani90@yahoo.com 2. The purpose of the data request, stated clearly. 3- If confirmed by the main executor, immediately proceed.

Comments