Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effectiveness of drain in pain control in women who need laparoscopic ovarian cystectomy surgery in two groups with drain and without drain

Protocol summary

Study aim

Determining the effect of drain in pain control after laparoscopic ovarian cystectomy surgery in women at Afzalipur Hospital, Kerman.

Design

A clinical trial with a control group, with parallel groups, a blind strain, randomized, on nodes of 130 intervention and control people, rand function of Excel software was used for randomization.

Settings and conduct

This study will be conducted in Afzalipur Hospital, Kerman, on patients with ovarian cysts. After randomizing the patients, the patient group will be determined using a sealed envelope, and the patients will be blinded to the study

Participants/Inclusion and exclusion criteria

Women aged 18 to 62 without any comorbidities who will undergo cystectomy surgery for ovarian cysts in Afzalipur Hospital and have no complications during the operation and are fully awake will be included in the study after obtaining written informed consent. People with a history of abdominal and thoracic surgery, psychiatric patients, those with chronic pain in the abdomen, pelvis, systemic disease, fallopian tube abscess (before or during surgery), shoulder pain and trauma, and patients whose laparoscopic surgery is changed to laparotomy and Patients who require a drain due to organ damage, bleeding or infection will be excluded from the study.

Intervention groups

260 women aged 18 to 62 who are candidates for laparoscopic surgery for ovarian cystectomy in Afzalipur Hospital, Kerman, will undergo surgery after being randomly assigned to control and intervention groups of 130 people and after the end of the surgery in the intervention group (with a drain), the Hemovac type drain is placed in place for 24 hours and the drain is removed after 24 hours.In the group without drain, the surgical procedures are completely similar.But in the end, the surgery will end without the insertion of a drain.

Main outcome variables

Patient pain score after surgery

General information

Reason for update

260 patients were examined.

Acronym

IRCT registration information

IRCT registration number: **IRCT20230130057275N1**
Registration date: **2023-03-14, 1401/12/23**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-09, 1402/05/18**
Update count: **1**

Registration date

2023-03-14, 1401/12/23

Registrant information

Name

Nafiseh Seyedi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-22, 1401/11/02

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of drain in pain control in women who need laparoscopic ovarian cystectomy surgery in two groups with drain and without drain

Public title

Investigating the effect of drain in pain control after laparoscopic cystectomy surgery in women referred to Afzalipur Hospital, Kerman

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 18 to 62 without any comorbidities who will undergo laparoscopic ovarian (LOC) for ovarian cysts from January to March 1401 in Afzalipur University Hospital and have no complications during the operation will be studied Full consciousness providing informed written consent not using analgesic before surgery

Exclusion criteria:

History of abdominal and thoracic surgery psychiatric patients those with chronic pain in the abdomen, pelvis, systemic disease, fallopian tube abscess (before or during surgery), shoulder pain and trauma Patients whose laparoscopic surgery is changed to laparotomy Patients who need a drain due to organ damage, bleeding or infection will be excluded from the study Patients who develop complications (fever, bleeding, infection at the incision site, atelectasis, subcutaneous emphysema) will also be excluded from the pain intensity study and will be studied only to compare and determine the effect of the drain on the complications

Age

From **18 years** old to **62 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **260**

Randomization (investigator's opinion)

Randomized

Randomization description

The sample number of 260 people will be selected as available and will be randomly divided into two groups of 130 people using random list software. Informed consent will be obtained from all patients of both groups. After the research is approved by the ethics committee, the subjects will be divided into two groups completely randomly using envelopes. For this purpose, envelopes are considered for the number of patients and the code related to the study group is placed inside the envelopes, then with each patient's visit, a specific code is assigned to each patient and his code is written on a random envelope. to be The envelope for each person will be opened at the beginning of the surgery, and based on that, each person will be assigned to the desired group. Randomization will be done by someone outside the research, this person and no other person will be aware of the contents inside the envelopes. Due to the nature of the study, it is not possible to blind the interventionist, but the surgeon was not aware of the patient group until the end of the study, and in order to reduce and minimize the bias, other information will be collected by another researcher after the surgery.

Blinding (investigator's opinion)

Single blinded

Blinding description

Randomization will be done by someone outside the research, this person and no other person will be aware of the contents inside the envelopes. Due to the nature of the study, it is not possible to blind the interventionist, but the surgeon was not aware of the patient group until the end of the study, and in order to reduce and minimize the bias, other information will be collected by another researcher after the surgery.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Medical University Campus,Haft-Bagh Highway, Kerman, Iran

City

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Province

Kerman

Postal code

7616913555

Approval date

2023-01-21, 1401/11/01

Ethics committee reference number

IR.KMU.AH.REC.1401.248

Health conditions studied

1

Description of health condition studied

Ovarian cyst

ICD-10 code

N83.29

ICD-10 code description

Other ovarian cysts

Primary outcomes

1

Description

The primary outcome of the study is the pain score, which is collected through the VAS questionnaire.

Timepoint

VAS pain questionnaire will be measured at 4 hours, 12 hours, 24 hours, 42 hours and 72 hours after surgery.

Method of measurement

Visual Analog Scale for Pain (VAS)

Secondary outcomes

1

Description

Time to work the bowels

Timepoint

Last hours after surgery

Method of measurement

data collection form through patient declaration

2

Description

Days of stay in the hospitalization

Timepoint

hospitalization days after surgery

Method of measurement

Investigation of Medical Record

3

Description

location of pain

Timepoint

4 hours, 12 hours, 24 hours, 42 hours and 72 hours after surgery

Method of measurement

History and interview with the patient and physical examination

Intervention groups

1

Description

Intervention group (with drain): Patients will be anesthetized before the start of laparoscopy. The patients will be operated by a surgical team. All patients will be given intravenous cefazolin 1 gram as a prophylactic antibiotic after induction of general anesthesia. General anesthesia will be performed using common anesthetic drugs used in Afzalipur Kerman Hospital. Laparoscopic surgery will be performed using carbon dioxide gas and three ports or incisions will be made as follows. One 10.5 mm incision below the umbilical cord to enter the telescope and two 5.5 mm incisions through the outer edge of the rectum to enter the surgical instrument. CO2 gas enters the peritoneum with an initial pressure of 12 to 16 mm Hg. After the end of the surgery in this group, before closing the skin and suture of the surgical site, a Hemovac type drain was inserted through a 5.5 mm side incision without any additional incision and placed in a suitable place in the surgical site. After that, the rest of the incision is sutured with surgical thread. The drain is placed in place for 24 hours and after that, the drain will be removed.

Category

Treatment - Surgery

2

Description

Control group (without drain): Patients will be operated by a surgical team. All patients will be given intravenous cefazolin 1 gram as a prophylactic antibiotic after induction of general anesthesia. General anesthesia will be performed using common anesthetic drugs used in Afzalipur Kerman Hospital. Laparoscopic surgery will be performed using carbon dioxide gas and three ports or incisions will be made as follows. One 10.5 mm incision below the umbilical cord to enter the telescope and two 5.5 mm incisions through the outer edge of the rectum to enter the surgical instrument. CO2 gas enters the peritoneum with an initial pressure of 12 to 16 mm Hg. After the end of the surgery in the control group, the surgery will be completed without the insertion of the drain.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Ghazal Mansouri

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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?
Yes
Title of funding source
Kerman 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

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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
Not applicable