Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Safety and efficacy of ovarian suspension loop: an assembled device for ovarian lifting and immobilization during laparoscopic cystectomy

Protocol summary

Study aim
evaluation of safety and efficacy of an assembled loop for ovarian lifting and immobilization during laparoscopic cystectomy

Design
This study is a parallel-group double-blind, randomized controlled trial. 30 women with ovarian cysts will be randomly divided into two groups of 15 each using a table of random numbers.

Settings and conduct
The present study is a clinical trial study. The study population in this study is women with ovarian cysts who undergo laparoscopic surgery. The setting of the study is Hazrat-e Rasool Akram affiliated with Iran University of Medical of Science. The objectives of the study are explained to women and written consent is obtained. 30 women will be divided into intervention and control groups (15 people in each group) using a random number table.

Participants/Inclusion and exclusion criteria
The participants will be premenopausal women with ovarian cyst

Intervention groups
An intervention group is a group in which the ovarian suspension loop is used to lift and immobilize the ovary during laparoscopic cystectomy.

Main outcome variables
The primary outcome will be the surgical time and ease of use for surgeons.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160527028109N3**
Registration date: **2021-04-26, 1400/02/06**
Registration timing: **registered_while_recruiting**
Last update: **2021-04-26, 1400/02/06**
Update count: **0**

Registration date
2021-04-26, 1400/02/06

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-21, 1400/02/01

Expected recruitment end date
2021-09-22, 1400/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Safety and efficacy of ovarian suspension loop: an assembled device for ovarian lifting and immobilization during laparoscopic cystectomy

Public title
Safety and efficacy of ovarian lifting and immobilization during laparoscopic cystectomy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Premenopausal women women with ovarian cyst

Exclusion criteria:

unwillingness to cooperate at the study

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation in this study is limited to intervention and control groups using randomization. Random allocation law is the simplest and most limited method of randomization. This method represents a large block for the total sample size. For this purpose, the researchers first determine a total sample size and then randomly divide a set of them into groups A and B. For example, in this study with a sample size of 26 people. 13 balls for intervention group A and 13 balls for intervention group B are placed inside a lottery container and then the balls are randomly removed from the container and a sequence is created. This method is used for two- or multi-group experiments.

Blinding (investigator's opinion)

Double blinded

Blinding description

The outcome assessor and data analyst will not know how the groups are assigned. But because patients' consent must be obtained, the patient knows in which group. For this purpose, before random allocation, a complete explanation of the interventions is given and the patient is told that they will be randomly placed in one of the groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran

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Province

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1449614535

Approval date

2020-11-11, 1399/08/21

Ethics committee reference number

IR.IUMS.REC.1399.789

Health conditions studied

1

Description of health condition studied

Reduce surgical time

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

How long it takes for an ovarian cyst to come out

Timepoint

During the surgery

Method of measurement

Chronometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Women with ovarian cysts, in which ovarian loops are used during laparoscopic surgery. To assemble the ovary suspension ring, depending on the thickness of the abdominal wall, about 25-35 cm of nylon suture is cut and also, depending on the length of the mesarium, about 8 to 12 cm is cut from the scalp vein catheter tube. The nylon thread is then passed through the scalp vein catheter and tied to create a loop at both ends. The node can be placed inside the catheter to hide. The assembled device is guided through one of the laparoscopic portals to the pelvic cavity and under the camera, along with the mapping of the abdominal surface, to the best point of placement of the ovarian cyst. The facial clouser is then inserted and the nylon thread is guided to the jaw. The facial clouser is pulled out of the abdomen and held in place by the Kelly clamp to prevent it from slipping back into the abdomen. The two ends of the tube catheter are taken with two graspers and guided under the ovary containing the cyst,

and after ensuring the correct placement, the amount of lifting with Kelly is guided out of the abdomen and fixed. It should be noted that excessive stretching causes impaired blood flow to the ovaries, so excessive tension should be avoided and a cystectomy can be performed.

Category

Treatment - Surgery

2

Description

Control group: Women with ovarian cysts, in which ovarian loops aren't used during laparoscopic surgery.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram hospital

Full name of responsible person

Kobra Tahermanesh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Seyed Abbas Motevalian-Vice President for Research of Iran University of Medical Sciences

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Kobra Tahermanesh

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
There is no more information
When the data will become available and for how long
After article publishing
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
There is no more information
From where data/document is obtainable
main investigator
What processes are involved for a request to access data/document
There is no more information
Comments