Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Comparing the effect of vicryle suture and v-lock suture using for vaginal cuff repair on incidence of post laparoscopic hysterectomy complications.

Protocol summary

Study aim
Comparing the effect of vicryle suture and v-lock suture using for vaginal cuff repair on incidence of post laparoscopic hysterectomy complications

Design
This research is a randomized clinical trial with a control group, parallel, double-blind, and 30-member groups in each group.

Settings and conduct
This study is carried out at Rasoul-e-Akram Hospital in Tehran. During surgery, the amount of bleeding and the time of surgery from the time of cutting the skin and entering the trowel until the end of surgery and sewing the skin, as well as the duration of vaginal cavity restoration in the two groups, will be investigated. All patients are referred to the laparoscopy clinic after transfer to the women's department for bleeding and after discharge for two routine follow-ups and vaginal examination at intervals of 1 and 3 months after surgery, and will be investigated for the complications of vaginal cuff.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1) 65 years of age 2) hysterectomy due to benign uterine 3) the absence of prolapse of grade 3 and 4 4) the absence of a body mass index above 35, 5) lack of internal diseases Exclusion criteria: 1) age over 65 years 2) pelvic prolapse grade 3 or 4 3) obesity (BMI) higher than 35 4) conditions that impair wound healing is: malnutration, anemia, DM, immuno compmised,smoking, steroids cansumation, rheumatologic disease, internal disease

Intervention groups
Intervention Group: suturing vaginal cuff during laparoscopic hysterectomy with v lock Control Group: suturing vaginal cuff during laparoscopic hysterectomy with vicryle

Main outcome variables
Complications caused by suturing vaginal cuff

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT2017013123666N5**
Registration date: **2017-02-28, 1395/12/10**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-02, 1397/03/12**
Update count: **1**

Registration date
2017-02-28, 1395/12/10

Registrant information

Name
Abolfazl Mehdizadeh kashi

Name of organization / entity
Iran University of Medical Science

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Iran university of medical scince

Expected recruitment start date
2017-01-24, 1395/11/05

Expected recruitment end date
2018-01-25, 1396/11/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effect of vicryle suture and v-lock suture using for vaginal cuff repair on incidence of post laparoscopic hysterectomy complications.

Public title
Comparison the effect of vicryle suture and v-lock suture for repairing vaginal cuff

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
65 years of age hysterectomy due to benign uterine the absence of prolapse of grade 3 and 4 the absence of a body mass index above 35 lack of internal diseases
Exclusion criteria:
age over 65 years pelvic prolapse grade 3 or 4 obesity (BMI) higher than 35 conditions that impair wound healing is: malnutration, anemia, DM, immuno compmised,smoking, steroids cansumation, rheumatologic disease, internal disease

Age
From **17 years** old to **65 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization was performed using the "= RANDBETWEEN(1,60)" function in excel software. So that the patients are assigned to two intervention and control groups before the surgery, after the informed consent.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study is done in double blind, so that subjects and outcome evaluator do not know the allocation of the two groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran University of Medical Science
Street address
Iran . Tehran . Hemat Highway . Milad Tower
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Province
Tehran
Postal code
1449614535

Approval date
2017-01-23, 1395/11/04

Ethics committee reference number
IR.IUMS.REC 1395.95-03-218-29659

Health conditions studied

1

Description of health condition studied
complication of vaginal cuff

ICD-10 code
N99.9

ICD-10 code description
Other disorders of the genitourinary system

Primary outcomes

1

Description
vaginal bleeding

Timepoint
3 months after surgery

Method of measurement
visit and reports

2

Description
infection of vaginal cuff

Timepoint
3 months after surgery

Method of measurement
visit and reports

3

Description
Dehiscence of vaginal cuff

Timepoint
3 months after surgery

Method of measurement
visit and reports

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: in this group suturing vaginal cuff during laparoscopic hysterectomy will done with v lock
Category
Treatment - Surgery

2

Description
Control Group: In this group suturing vaginal cuff during laparoscopic hysterectomy will done with vicryle
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul-e-akram hospital- womens unit
Full name of responsible person
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Sponsors / Funding sources

1

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Name of organization / entity
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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 Science
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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