

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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: malnutrition, anemia, DM, immuno compromised, smoking, steroids consumption, 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

Country

Iran (Islamic Republic of)

Phone

+98 216651500

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Recruitment status

Recruitment complete

Funding source

Iran university of medical science

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: malnutrition, anemia, DM, immuno compromised, smoking, steroids consumption, 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

City

Tehran

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

Abolfazal Mehdizadeh kashi

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Niayesh Av. Sattar khan st. Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

kazem malakouti

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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

Full name of responsible person

Dr. mania kaveh

Position

Resident of Obstetrics and Gynecology

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Subspecialist

Other areas of specialty/work

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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