

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparision of two methods of vaginal cuff clouser during laparoscopy hysterectomy:A new technique

Protocol summary

Summary

The study population is comprised women at reproductive and premenopausal ages whom refer to gynecology clinic in Rasool-e Akram Tertiary and a private Hospitals in Tehran. The candidates will be select for total laparoscopy hysterectomy and bilateral salpingo-oophorectomy. Any vaginal infection that reveals by examination will be treated. The exclusion criteria's are: patients with recent history like smoking, diabetes, mellitus, immune deficiency, vascular diseases, coagulation disorders, consuming corticosteroids, abnormal Pap smear and suspicious to cancer and menopausal women. Patients who have inclusion criteria's after filling of consent form, by using the randomization table randomly assigned to two groups: 1) conventional and 2) new techniques for vaginal cuff closure. Patients were not aware of the type of intervention they performed on them. After placement of 11 mm umbilical trocar and two 5 mm lateral and 11 mm suprapubic trocars, under general anesthesia, every bites are cut by ligasure or bipolar and scissors. After the securing the angle of incision, a full thickness needle bite is taken suturing 1 cm away from the margin of the incision and coming out at 0.5 cm from the edge of the vaginal epithelium. After then, the entering perform at 0.5 cm to the vaginal epithelium of opposite edge and come out 1 cm away from of the margin of the incision in oblique fashion. A superficial bite is taken encircling the outer margins without biting vaginal epithelium. Base of length of the cuff, 3-5 stiches are running the same fashion. The patients will be discharge after 48 hours and educate for amount of vaginal bleeding. If the 1/4, 1/2 or entire of the pad is being wet, the volume of bleeding is classified to low, moderate and severe. The patient will be follow in three month by phone call. Every week for six weeks and then biweekly. If the patients have any severe vaginal bleeding, profuse or malodor vaginal discharge, fever and chills, it is recommended to refer to our GYN clinic.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052728109N1**

Registration date: **2017-07-18, 1396/04/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-18, 1396/04/27

Registrant information

Name

Kobra Tahermanesh

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6435 2562

Email address

tahermanesh.k@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research & Technology, Iran University of Medical Scienes (IUMS)

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-10-30, 1397/08/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of two methods of vaginal cuff clouser during laparoscopy hysterectomy:A new technique

Public title

Comparision of two methods of vaginal cuff clouser during laparoscopy hysterectomy

Purpose

Treatment

Inclusion/Exclusion criteria

The exclusion criteria's are: patients with recent history like smoking, diabetes, mellitus, immune deficiency, vascular diseases, coagulation disorders, consuming corticosteroids, abnormal Pap smear and suspicious to cancer and menopausal women.

Age

From **17 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences (IUMS)

Street address

Hemmat Highway, Iran University of Medical Sciences (IUMS)

City

Tehran

Postal code

Approval date

2017-05-14, 1396/02/24

Ethics committee reference number

IR.IUMS.REC1395.95-03-218-29670

Health conditions studied

1

Description of health condition studied

Hysterectomy

ICD-10 code

O82.2

ICD-10 code description

Delivery by caesarean hysterectomy

Primary outcomes

1

Description

Bleeding

Timepoint

After hysterectomy until the 3 months

Method of measurement

tampons

Secondary outcomes

1

Description

prolaps

Timepoint

After hysterectomy until the 3 months

Method of measurement

visit

Intervention groups

1

Description

intervention group: surgery with new method control group: surgery with common method

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul-e Akram Tertiary Hospital

Full name of responsible person

Banafsheh Tajbakhsh

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Farmanieh Hospital

Full name of responsible person

Elham Akbari

Street address

Famarieh Hospital, Farmanieh Blvd
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Administration of Iran University
of Medical Sciences (IUMS)

Full name of responsible person

Dr. Kobra Tahermanesh

Street address

Rasoul-e Akram Tertiary Hospital

City

Tehran

Grant name

Grant code / Reference number

95-03-218-29670

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Administration of Iran University of
Medical Sciences (IUMS)

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Rasoul-e Akram Tertiary Hospital

Full name of responsible person

Banafsheh Tajbakhsh

Position

Fellowship of Minimally Invasive Gynecology

Other areas of specialty/work

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inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty