Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Comparative study of the success rate and complications of abdominal sacrohysteropexy with abdominal uterosacral in the treatment of uterine prolapses (a clinical trial)

Protocol summary

Study aim

Comparative study of the success rate and complications of abdominal sacrohysteropexy with abdominal uterosacral

Design

This is a non-blinded randomized clinical trial with a parallel design. It will be conducted on 15 women candidates for surgery. A random block is used for randomization and the participants are assigned to two intervention groups.

Settings and conduct

In this unblinded study, patients are treated with enoxaparin subcutaneously 12 hours before surgery and two grams of Keflin are injected as prophylaxis half an hour before surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent; Patients with complaints of uterine-vaginal prolapse who want to preserve the uterus Exclusion criteria: Urinary incontinence; History of pelvic prolapse surgery Malignancy or dysplasia on Pap smear; Immune system disorders, blood or coagulation disorders

Intervention groups

In the first intervention group, after entering the abdomen, the sigmoid colon is pushed aside, and the location of the ureters is determined. The peritoneum is pushed aside on the promontory of the sacrum. In the area of the cervix and the back of the uterus, after separating the serous tissue, a polypropylene mesh with dimensions of 5 x 15 cm is connected to the back of the cervix and uterus and is connected to the promontory of the sacrum, and finally, the abdominal layers are closed. In the second intervention group, after opening the abdominal layers, the location of the uterosacral ligaments is determined, it is carefully separated from the ureters, and the uterus is connected to the uterosacral ligaments. Before closing the abdominal layers, the health of the ureters is ensured by performing a cystoscope, and then the abdominal layers are repaired in anatomical order.

Main outcome variables

The success of middle compartment surgery (bleeding rate, dyspareunia after surgery)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N206**
Registration date: **2023-08-11, 1402/05/20**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-11, 1402/05/20**
Update count: **0**

Registration date

2023-08-11, 1402/05/20

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-11, 1402/05/20

Expected recruitment end date
2025-05-10, 1404/02/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the success rate and complications of abdominal sacrohysteropexy with abdominal uterosacral in the treatment of uterine prolapses (a clinical trial)

Public title
Comparative study of the success rate and complications of abdominal sacrohysteropexy with abdominal uterosacral in the treatment of uterine prolapses
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent Patients with complaints of uterine-vaginal prolapse who want to preserve the uterus. Patients who are candidates for one of two abdominal sacrohysteropexy and abdominal high uterosacral suspension surgeries.
Exclusion criteria:
urinary incontinence History of pelvic prolapse surgery Malignancy or dysplasia on Pap smear Immune system disorders, blood or coagulation disorders Contraindications to surgery Abnormal uterine bleeding Having a long cervix during examination
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization using the blocking method with blocks in sizes 6 and 9. For randomization, the site https://www.sealedenvelope.com is used. All codes are recorded on paper and stored in specific envelopes. Each of the generated codes is kept separately inside the envelope and the secretary gives one of these envelopes to the patient before the patient enters the doctor's room. Accordingly, the next patient code is not predictable. The doctor determines which treatments to perform based on the patient's code. Only the physician performing the intervention will be aware of the code assigned to the patient. After evaluating the outcome, based on the patient's name, the collected information will be linked to the assigned code.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Approval date
2023-06-18, 1402/03/28
Ethics committee reference number
IR.KUMS.MED.REC.1402.117

Health conditions studied

1

Description of health condition studied
Uterine prolapse
ICD-10 code
N81.4
ICD-10 code description
Uterovaginal prolapse, unspecified

Primary outcomes

1

Description
The success of middle compartment surgery
Timepoint
At the beginning of the study and 12 months after surgery
Method of measurement
by the doctor (the distance between the point C and the hymen)

2

Description

Excretory and urinary complications

Timepoint

At the beginning of the study and 12 months after surgery

Method of measurement

Ask the patient

Secondary outcomes

empty

Intervention groups

1

Description

In the first intervention group (abdominal sacral hysteropexy method), after entering the abdomen, the sigmoid colon is pushed aside, and the location of the ureters is determined. The peritoneum is pushed aside on the promontory of the sacrum. In the area of the cervix and the back of the uterus, after separating the serous tissue, a polypropylene mesh with dimensions of 5 x 15 cm is connected to the back of the cervix and uterus and is connected to the promontory of the sacrum, and finally, the abdominal layers are closed.

Category

Treatment - Surgery

2

Description

In the second intervention group (abdominal uterosacral method), after opening the abdominal layers, the location of the uterosacral ligaments is determined, it is carefully separated from the ureters, and the uterus is connected to the uterosacral ligaments. Before closing the abdominal layers, the health of the ureters is ensured by performing a cystoscope, and then the abdominal layers are repaired in anatomical order.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Tahereh Parsajam

Street address

Emam Reza Hospital, Parastar Boulevard

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Email

t.parsajam6368@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Cyrus Jalili

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Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Tahereh Parsajam

Position

Resident Gynecology and Obstetrics

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Firoozeh Veisi
Position
Member of the academic staff of Kermanshah University of Medical Sciences
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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Resident Gynecology and Obstetrics
Latest degree
Medical doctor
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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 further 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
No - There is not 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