Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the success rate in urinary evacuation after women's anterior colporrhaphy surgeries using two methods: spontaneous urinary evacuation and retrograde bladder filling.

Protocol summary

Study aim

Determination of urine volume for evaluation of urine voiding after anterior colporrhaphy surgery

Design

A phase I randomized, unblinded, two-intervention, parallel-group clinical trial on 110 patients, using sealed envelopes and a random number table for randomization.

Settings and conduct

In this clinical trial, 110 patients who were candidates for anterior colporrhaphy at Kowsar Women's Hospital in Urmia were randomly enrolled in the study and were divided into two groups without blinding to determine urine volume to evaluate bladder emptying after anterior colporrhaphy surgeries.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pvr more than 150cc، patients with urinary tract damage that needs catheterization before surgery, detrusor muscle weakness at urodynamic test before surgery

Intervention groups

People who undergo anterior colporrhaphy fall into 2 groups: In group 1, the urinary catheter will be removed immediately after the surgery is completed and before the patient wakes up from anesthesia. Patients will be monitored for 6 hours and urinary function will be considered successful if they pass at least 150 ml of urine during the corresponding time.In group 2, patients will be discharged from the operating room with a urinary catheter, and the bladder will be filled with 300 ml of normal saline after the patients wake up from anesthesia, and then the urinary catheter will be removed. Patients should then be monitored for urinary function over a period of sixty minutes.

Main outcome variables

Age, BMI, parity, previous surgical history, preoperative PVR, postoperative PVR, surgical duration, urinary function success, urine output, full and empty bladder volume, postoperative urinary retention, length of stay, complications, need for catheterization after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250621066214N1**
Registration date: **2025-07-12, 1404/04/21**
Registration timing: **prospective**

Last update: **2025-07-12, 1404/04/21**
Update count: **0**

Registration date

2025-07-12, 1404/04/21

Registrant information

Name

elham rajabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-21, 1404/04/30

Expected recruitment end date

2026-06-30, 1405/04/09

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the success rate in urinary evacuation after women's anterior colporrhaphy surgeries using two methods: spontaneous urinary evacuation and retrograde bladder filling.

Public title
Comparison of the success rate in urinary evacuation after women's anterior colporrhaphy surgeries using two methods: spontaneous urinary evacuation and retrograde bladder filling.
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
Patients candidates for anterior colporrhaphy for pelvic organ prolapse surgeries or urinary incontinence. Age over 18 years Satisfaction regarding participation in the study
Exclusion criteria:
Patients who require catheterization before surgery due to urinary system damage. PVR above 150 milliliters Hypofunction of the detrusor muscle in preoperative urodynamic studies.
Age
From **18 years** old to **65 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **110**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was done simply and individually by selecting from a sealed envelope.
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 urmia University of Medical Sciences
Street address
Resalat ave
City
Urmia
Province
West Azarbaijan
Postal code
5715755787
Approval date
2025-05-27, 1404/03/06
Ethics committee reference number
IR.UMSU.REC.1404.051

Health conditions studied

1

Description of health condition studied
Cystocele
ICD-10 code
N81.11
ICD-10 code description
Cystocele, midline

Primary outcomes

1

Description
Rate of success in emptying urine after anterior Colporrhaphy
Timepoint
Three hours after surgery and four days after discharge
Method of measurement
Nelaton catheter and measuring cup

Secondary outcomes

1

Description
Rate of urine infection after surgery
Timepoint
30 day after surgery
Method of measurement
Urin analysis and patient symptoms

Intervention groups

1

Description
Intervention group1: Backfilling the bladder with 300 cc of normal saline, then removing the Foley catheter and allowing the patient to void urine for one hour and checking the amount of urine excreted.
Category
N/A

2

Description
Intervention group2: Removing the Foley catheter without filling the bladder with normal saline and allowing the patient to void within 6 hours
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Hospital Urmia
Full name of responsible person
Doctor Elham Rajabi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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research@umsu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Dr.Negar Alizade
Position
Obstetrics and Gynecology Resident
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Person responsible for updating data

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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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable