# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Comparison of the effect of 1 versus 3 days post operative urinary catheterization after anterior colporrhaphy on urinary complications

## Protocol summary

**Summary**

After colporhaphy , folley catheterization is done for the patients with sutures on vaginal mucosa for prevention of urinary retention. Folley can cause urinary tract infection and pain. This study is a randomized controlled trial.Inclusion criteria:BMI:19-24, grade 1 and 2 of vaginal prolapse, Normal urine culture and analysis, agree to participate in the study. Exclusion criteria: diabetic patients. Eighty eight patients that refer to gynecology clinics of Bushehr University of Medical Sciences during 2015, randomly divide in two groups. In control group folley inserted for 72 hours and in intervention group for 24 hours after operation.urinary tract infection will be checked with urine culture and urine analysis.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201506134339N11**
Registration date: **2015-07-26, 1394/05/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2015-07-26, 1394/05/04

**Registrant information**

**Name**

Elham Rahmani

**Name of organization / entity**

Bushehr University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 77125265914

**Email address**

rahmani@bpums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

vice Chanceller of reseach ,Bushehr University of Medical sciense

**Expected recruitment start date**

2015-05-22, 1394/03/01

**Expected recruitment end date**

2016-05-21, 1395/03/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of 1 versus 3 days post operative urinary catheterization after anterior colporrhaphy on urinary complications

**Public title**

comparison of the effect of 1 versus 3 days urinary catheterization after gynecological operation on urinary complications

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

inclusion criteria:vaginal prolapse grade 1 and 2; U/A & U/C normal; BMI 19 -24; intention to participation.
exclusion criteria:diabetic patient.

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **88**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**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**

Bushehr University of Medical Sciences

**Street address**

Bahmani campus, Bushehr University of Medical Sciences, Sabzabad Blvd, Bhmani.

**City**

Bushehr

**Postal code**

**Approval date**

2015-05-17, 1394/02/27

**Ethics committee reference number**

B-93-16-21

## Health conditions studied

### 1

**Description of health condition studied**

Urinary tract infection

**ICD-10 code**

N30-N39

**ICD-10 code description**

urinary infection complicating colporhaphy

## Primary outcomes

### 1

**Description**

urinary infection

**Timepoint**

24 and 72 hours after operation

**Method of measurement**

Urine analysis and culture

## Secondary outcomes

### 1

**Description**

number of urinary catheterization

**Timepoint**

24 and 72 hours after operetion

**Method of measurement**

hospital records

### 2

**Description**

urinary retention

**Timepoint**

24 and 72 hours after operetion

**Method of measurement**

checking for residual urine

### 3

**Description**

duration of addmision

**Timepoint**

24 and 72 hours after operetion

**Method of measurement**

hospital record

### 4

**Description**

satisfaction of the patient

**Timepoint**

24 and 72 hours after operetion

**Method of measurement**

quastionare

## Intervention groups

### 1

**Description**

intervention group: removal of urinary catheter 24 hours after operation

**Category**

Treatment - Devices

### 2

**Description**

control group: removal of urinary catheter 72 hours after operation

**Category**

Treatment - Devices

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Gynecology clinics of Bushehr University of Medical Sciences

**Full name of responsible person**

Dr Elham Rahmani
**Street address**
**City**
Bushehr

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
vice Chanceller of reseach ,Bushehr University of Medical sciense
**Full name of responsible person**
Dr Afshin Ostovar
**Street address**
Bahmani campus, Bushehr University of Medical Sciences, Sabzabad Blvd, Bhmani.
**City**
Bushehr
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
vice Chanceller of reseach ,Bushehr University of Medical sciense
**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**
Bushehr University of Medical Sciences
**Full name of responsible person**
Dr Elham Rahmani
**Position**
associate professor of OB -GYN
**Other areas of specialty/work**
**Street address**
Bahmani campus, Bushehr University of Medical Sciences, Sabzabad Blvd, Bahmani.
**City**
Bushehr
**Postal code**
**Phone**
00
**Fax**
**Email**
rahmani@bpums.ac.ir
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Bushehr university of Medical Sciences
**Full name of responsible person**
Dr Elham Rahmani
**Position**
associate professor of OB -GYN
**Other areas of specialty/work**
**Street address**
Bahmani campus, Bushehr University of Medical Sciences, Sabzabad Blvd, Bhmani.
**City**
Bushehr
**Postal code**
**Phone**
00
**Fax**
**Email**
rahmani@bpums.ac.ir
**Web page address**

## Person responsible for updating data

**Contact**

## 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*