

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

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

#### Protocol summary

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#### Summary

After colporrhaphy, Foley catheterization is done for the patients with sutures on vaginal mucosa for prevention of urinary retention. Foley 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 Foley 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.

#### Recruitment status

**Recruitment complete**

#### Funding source

vice Chancellor of research, Bushehr University of Medical Science

#### 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

#### 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

#### 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 colpohaphy

## 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 operation

#### Method of measurement

hospital records

### 2

#### Description

urinary retention

#### Timepoint

24 and 72 hours after operation

#### Method of measurement

checking for residual urine

### 3

#### Description

duration of admision

#### Timepoint

24 and 72 hours after operation

#### Method of measurement

hospital record

### 4

#### Description

satisfaction of the patient

#### Timepoint

24 and 72 hours after operation

#### Method of measurement

questionare

## 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

**City**  
Bushehr  
**Postal code**  
**Phone**  
00  
**Fax**  
**Email**  
rahmani@bpums.ac.ir  
**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
vice Chancellor of reseach ,Bushehr University of  
Medical science  
**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 Chancellor of reseach ,Bushehr University of Medical  
science  
**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.

#### Person responsible for scientific inquiries

##### Contact

**Name of organization / entity**  
Bushehr university of Medical Sciences  
**Full name of responsible person**  
Dr Elham Rahmani  
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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*