

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Preventive effect of tamsulosin on postoperative urinary retention and obstructive urinary symptoms in colporrhaphy surgery

#### Protocol summary

##### Summary

Aim of this study is to assess preventive effect of Tamsulosin on postoperative urinary retention and obstructive urinary symptoms in colporrhaphy surgery. This study is clinical trial and double blind. Inclusion criteria: less than 60 years; indications for colporrhaphy surgery; lack of active urinary tract infection; lack of history of neurological disorders; lack of malignancy; lack of urinary incontinence; don't use of drugs affecting the performance of urination; lack of urology disorder;lack of history of urinary stones or urinary obstruction;don't urinary catheter fixed; don't history of chronic kidney disease; don't history of cardiopulmonary disorders; don't history of allergy to Tamsulosin; don't history of treatment and use Tamsulosin. Exclusion criteria: Lack of access to patient for any reason during the first 24 hours after surgery. We will divide patients in 2 group after complete demographic information (age and gender). We will prescribe 0.4 milligram Tamsulosin one dose at 12 PM o'clock after surgery in 65 patients. We will prescribe placebo to control group. We will examine difficulty in urination or retention in 24 hours after surgery by clinical response.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017042720258N42**

Registration date: **2017-04-29, 1396/02/09**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-04-29, 1396/02/09

##### Registrant information

##### Name

Fariba Farokhi

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3222 2003

##### Email address

f.farokhi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor and Research ,Arak University of Medical Sciences

##### Expected recruitment start date

2017-02-07, 1395/11/19

##### Expected recruitment end date

2018-03-10, 1396/12/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Preventive effect of tamsulosin on postoperative urinary retention and obstructive urinary symptoms in colporrhaphy surgery

##### Public title

Preventive effect of tamsulosin on postoperative urinary retention and obstructive urinary symptoms in colporrhaphy surgery

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria:less than 60 years; Indications for colporrhaphy surgery; lack of active urinary tract

infection; lack of history of neurological disorders; lack of malignancy; lack of urinary incontinence; don't use of drugs affecting the performance of urination; lack of urology disorder;lack of history of urinary stones or urinary obstruction;don't urinary catheter fixed; don't history of chronic kidney disease; don't history of cardiopulmonary disorders; don't history of allergy to Tamsulosin; don't history of treatment and use Tamsulosin. Exclusion criteria: Lack of access to patient for any reason during the first 24 hours after surgery.

#### Age

To **60 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **130**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double 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 Arak University of Medical Sciences

##### Street address

Dr Mohammad Rafie, Vice Chancellor Research,  
Payambar Azam complex, Basij square, Sardasht,  
Arak

##### City

Arak

##### Postal code

38149578558

#### Approval date

2017-02-06, 1395/11/18

#### Ethics committee reference number

IR.ARAKMU.REC.1395.381

## Health conditions studied

### 1

#### Description of health condition studied

Urinary retention

#### ICD-10 code

R33

#### ICD-10 code description

Retention of urine

## Primary outcomes

### 1

#### Description

urinary retention

#### Timepoint

24 hour after surgery

#### Method of measurement

clinical response

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: We will prescribe 0.4 milligram  
Tamsulosin one dose at 12 PM o'clock after surgery

#### Category

Treatment - Drugs

### 2

#### Description

Control group: We will prescribe placebo at 12 PM o'clock  
to control group

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Taleghani hospital

##### Full name of responsible person

Dr Maryam Shokpour

##### Street address

Taleghani hospital, Arak

##### City

Arak

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor For Research, Arak University of  
Medical Sciences

##### Full name of responsible person

Dr Mohammad Rafiee

**Street address**

Vice Chancellor For Research, Payambar Azam  
Complex, Basij square, Sardasht, Arak

**City**

Arak

**Grant name**

-

**Grant code / Reference number**

-

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

Yes

**Title of funding source**

Vice Chancellor For Research, Arak University of Medical  
Sciences

**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**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Ali Cyrus

**Position**

Faculty, Urologist

**Other areas of specialty/work**

**Street address**

Valiasr Hospital, Arak

**City**

Arak

**Postal code**

3814957558

**Phone**

+98 86 3222 0003

**Fax**

+98 86 3471 3638

**Email**

Ali.cyrus@yahoo.com

**Web page address**

-

**Person responsible for scientific  
inquiries**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Maryam Shokrpour

**Position**

Faculty, Gynecologist

**Other areas of specialty/work**

**Street address**

Taleghani hospital, Arak

**City**

Arak

**Postal code**

3814957558

**Phone**

+98 86 3471 3638

**Fax**

+98 86 3417 3638

**Email**

Maryam\_shokpour@yahoo.com

**Web page address**

-

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Arak University of Medical Science

**Full name of responsible person**

Dr Elmira Shakiba

**Position**

resident of gynecologist

**Other areas of specialty/work**

**Street address**

Payamberazam Complex, Basij Square, Sardasht,  
Arak

**City**

Arak

**Postal code**

3814957558

**Phone**

+98 86 3417 3645

**Fax**

+98 86 3417 3638

**Email**

elmira\_sh55@yahoo.com

**Web page address**

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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*