

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Preventive effect of tamsulosin on postoperative urinary retention in benign perianal surgeries

#### Protocol summary

##### Summary

Aim of this study is preventive effect of tamsulosin on postoperative urinary retention in benign perianal surgeries. This study is clinical trial and double blinded. Inclusion criteria: 18-50 years; Indications for surgery hemorrhoidectomy; sphincterotomy; incisions; perianal abscess drainage and fistulotomy and fistulectomy. Exclusion criteria: active urinary tract infection; history of neurological disorders; malignancy; urinary incontinence; use of drugs affecting the performance of urination; urology disorder; prostate cancer; bladder cancer; history of urinary stones or urinary obstruction; benign prostatic hypertrophy; history of urology surgery; urinary catheter fixed; chronic kidney disease; cardiopulmonary disorders; history of allergy to Tamsulosin; history of treatment and use Tamsulosin. We will divide patients in three groups after complete demographic information (age and gender). We will prescribe 0.4 milligram Tamsulosin one dose 6 hours before surgery in 81 patient. We will prescribe 0.4 milligram Tamsulosin one dose 6 hours before surgery and 6 hours after surgery in 81 patient. We will prescribe placebo seems inversion groups. We will examine difficulty in urination or retention urination in 24 hours after surgery by clinical response.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016122720258N22**  
Registration date: **2017-01-04, 1395/10/15**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-01-04, 1395/10/15

#### 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 President of Research, Arak University of Medical Sciences

#### Expected recruitment start date

2016-06-08, 1395/03/19

#### Expected recruitment end date

2017-06-09, 1396/03/19

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Preventive effect of tamsulosin on postoperative urinary retention in benign perianal surgeries

#### Public title

Preventive effect of tamsulosin on postoperative urinary retention in benign perianal surgeries

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: 18-50 years; Indications for surgery hemorrhoidectomy; sphincterotomy; incisions; perianal abscess drainage and fistulotomy and fistulectomy

Exclusion criteria: active urinary tract infection; history of neurological disorders; malignancy; urinary incontinence; use of drugs affecting the performance of urination; urology disorder; prostate cancer; bladder cancer; history of urinary stones or urinary obstruction; benign prostatic hypertrophy; history of urology surgery; urinary catheter fixed; chronic kidney disease; cardiopulmonary disorders; history of allergy to Tamsulosin; history of treatment and use Tamsulosin.

#### Age

From **18 years** old to **50 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **243**

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

Randomize by table of random numbers

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee Arak University of Medical Sciences

##### Street address

Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

##### City

Arak

##### Postal code

38149578558

#### Approval date

2016-05-23, 1395/03/03

#### Ethics committee reference number

IR.ARAK.MU.REC.1395.54

## Health conditions studied

### 1

#### Description of health condition studied

benign perianal surgeries

#### ICD-10 code

D30

#### ICD-10 code description

Benign neoplasm of urinary organs

## 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 prescribe 0.4 milligram Tamsulosin one dose in 6 hours before surgery in 81 patient.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: We prescribe 0.4 milligram Tamsulosin one dose in 6 hours before surgery and 6 hours after surgery in 81 patient.

#### Category

Treatment - Drugs

### 3

#### Description

Control group: We prescribe Placebo seems intervention group in 81 patient.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Valiasr Hospital

##### Full name of responsible person

Dr Shahin Fateh

##### Street address

Valiasr square, Valiasr hospital

##### 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**

Shahid Shirodi street, Valiasr square, Valiasr hospital

**City**

Arak

**Postal code**

3814957558

**Phone**

+98 86 3222 2003

**Fax**

+98 863222003

**Email**

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 Shahin Fateh

**Position**

Faculty, Surgeon

**Other areas of specialty/work****Street address**

Shahid Shirodi street, Valiasr square, Valiasr hospital

**City**

Arak

**Postal code**

3814957558

**Phone**

+98 86 3222 2003

**Fax**

-

**Email**

sh.fateh@arakmu.ac.ir

**Web page address**

-

## Person responsible for updating data

**Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Yasaman Shariat

**Position**

resident of surgery

**Other areas of specialty/work****Street address**

Payambarazam complex, Basij square, Sardasht, Arak

**City**

Arak

**Postal code**

3814957558

**Phone**

+98 86 3222 2003

**Fax**

+98 863222003

**Email**

shariat@yahoo.com

**Web page address**

-

## 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*