

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