

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

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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

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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

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City

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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

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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