

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The efficacy of prophylactic tamsulosin in preventing acute urinary retention after benign anorectal surgeries

#### Protocol summary

##### Study aim

Prevention of acute urinary retention following anorectal surgery

##### Design

Clinical trial , community based, parallel group, double blind, randomised controlled trial

##### Settings and conduct

This study was conducted in Zanjan Hospital and participants through simple randomization divided into intervention and control groups, and double blind study.

##### Participants/Inclusion and exclusion criteria

Participants : Patients with benign anorectal diseases  
inclusion criteria : Both sexes - 20 to 70 years - Indication of hemorrhoidectomy and fistulotomy and sphincterotomy  
exclusion criteria : Urinary tract infection - history of neurological disorder - malignancy-urinary incontinence-previous use of tamsulosin

##### Intervention groups

intervention group percieve tamsulosin and control group percieve placebo before surgery

##### Main outcome variables

Prevention of urinary retention and urinary complications

#### General information

##### Reason for update

##### Acronym

ZSC

##### IRCT registration information

IRCT registration number: **IRCT20190115042363N1**

Registration date: **2019-04-21, 1398/02/01**

Registration timing: **retrospective**

Last update: **2019-04-21, 1398/02/01**

Update count: **0**

##### Registration date

2019-04-21, 1398/02/01

#### Registrant information

##### Name

Farhad Kheiri tootkaleh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3313 1851

##### Email address

farhadkheiri1986@gmail.com

#### Recruitment status

##### Recruitment complete

#### Funding source

##### Expected recruitment start date

2018-07-06, 1397/04/15

##### Expected recruitment end date

2019-03-19, 1397/12/28

##### Actual recruitment start date

2018-07-06, 1397/04/15

##### Actual recruitment end date

2019-03-19, 1397/12/28

##### Trial completion date

2019-03-19, 1397/12/28

#### Scientific title

The efficacy of prophylactic tamsulosin in preventing acute urinary retention after benign anorectal surgeries

#### Public title

The efficacy of prophylactic tamsulosin in preventing acute urinary retention after benign anorectal surgeries

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Both sexes 20 to 70 years Indication of hemorrhoidectomy and fistulotomy and sphincterotomy  
IPSS criteria less than 7

##### Exclusion criteria:

Urinary tract infection History of neurological disorder

Malignancy Urinary incontinence Use of medications that affect urination History of drug allergy to tamsulosin Recent Tamsulosin Uses

## Age

From **20 years** old to **70 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor

## Sample size

Target sample size: **140**

Actual sample size reached: **116**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization with a numbered echelon

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In order to prevent the onset of Bias, placebo was prescribed and blinded. In addition to the fact that the patient is not aware of his group, drug warranties and post-operative evaluation are also performed by a person who is unaware of the patient grouping.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Medical Ethics Committee of Zanjan University of medical science of Medical Sciences

##### Street address

Zanjan university of medical science, Zanjan

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4513956111

#### Approval date

2018-07-03, 1397/04/12

#### Ethics committee reference number

IR.ZUMS.REC.1397.82

## Health conditions studied

### 1

#### Description of health condition studied

hemorrhoid

#### ICD-10 code

K64

#### ICD-10 code description

Hemorrhoids and perianal venous thrombosis

## Primary outcomes

### 1

#### Description

Urinary retention

#### Timepoint

24 hours after surgery

#### Method of measurement

Clinical response

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients who received tamsulosin at a dose of 0.4 mg 12 hours before surgery

#### Category

Prevention

### 2

#### Description

Control group: Patients who received placebo 12 hours before surgery

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mousavi hospital

##### Full name of responsible person

Mohamad naeem bangash

##### Street address

General surgery department, Mousavi hospital, Gavazang Blvd, Zanjan Town

##### City

Zanjan

##### Province

Zanjan

##### Postal code

45139-56183

**Phone**  
+98 24 3313 0000  
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gps1376@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Dr Alireza shoghli  
**Street address**  
Zanjan University of medical sciences, Zanjan Town  
**City**  
Zanjan  
**Province**  
Zanjan  
**Postal code**  
45156-13191  
**Phone**  
+98 24 3315 6319  
**Email**  
research@zums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Zanjan University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Mohamad naeem bangash  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
General Surgery  
**Street address**  
General Surgery department, Mousavi hospital,

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Mohamad naeem bangash  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Farhad kheiri tootkaleh  
**Position**  
resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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**Province**  
Zanjan  
**Postal code**  
4513956183

**Phone**

+98 243313000

**Email**

farhadkheiri1986@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

Information will be made available to researchers

**When the data will become available and for how long**

Six months later and for two years

**To whom data/document is available**

for researcher

**Under which criteria data/document could be used**

With the permission of the researcher

**From where data/document is obtainable**

zanjan university of medical science

**What processes are involved for a request to access data/document**

Communication from the email with the researcher

**Comments**

Thank you for cooperating with IRCT