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
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Farhad Kheiri tootkaleh
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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

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

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr Alireza shoghli
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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
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
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Associate professor
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Person responsible for updating data

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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