

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of condom use on reducing the incidence of urinary retention after anorectal surgeries

Protocol summary

Study aim

Determining the Effect of Condoms on Prevention of Urinary Retention in Men Following Anorectal Surgery

Design

Clinical Trial

Settings and conduct

Swap to Persian Patients who undergo various surgeries due to anorectal problems are included in the study. Before surgery, they are examined at an outpatient clinic to diagnose diabetes, high blood pressure and heart disease. The IPSS questionnaire is completed for all patients and patients are divided into three groups based on the score of the questionnaire. (Patients with IPSS Low, Moderate, High). Patients with a history of duct stenosis, urinary stones, neurological disease, urinary incontinence and urinary tract infections, and history of surgical procedures on the urethra are currently excluded from the study. In order to blind, the examiner will be unaware of the grouping of patients. Swap to Persian Then, at the appointed time, each patient enters the operating room under standard monitoring. All patients fall under the spinal cord. The fluids received before and during surgery are the same for all patients (5 cc per kg body weight per hour) for each patient.

Participants/Inclusion and exclusion criteria

Patients who undergo various surgeries due to anorectal problems are included in the study. Patients with a history of duct stenosis, urinary stones, neurological disease, urinary incontinence and urinary tract infections, and history of surgical procedures on the urethra are currently excluded from the study.

Intervention groups

Patients who undergo various surgeries due to ano-rectal problems are randomly allocated in two groups. After the surgery for the patients in the intervention group condom sheets are applied and for the other group no instrument will be used.

Main outcome variables

Urinary retention; total dose of analgesic prescribed

(Ketorolac); total dose of narcotic prescribed (Pethidine)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180720040533N1**

Registration date: **2019-03-27, 1398/01/07**

Registration timing: **retrospective**

Last update: **2019-03-27, 1398/01/07**

Update count: **0**

Registration date

2019-03-27, 1398/01/07

Registrant information

Name

Farzad Vaghef Davari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2213 5448

Email address

fvdavari@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-12, 1397/07/20

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effect of condom use on reducing the incidence of urinary retention after anorectal surgeries

Public title
Investigating the effect of condom use on reducing the incidence of urinary retention after anorectal surgeries

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients who undergo various surgeries due to anorectal problems
Exclusion criteria:
Patients with history of narrowing of the urethra Patients with a history of urinary stones Patients with a history of urinary tract infection Patients with a history of neurological disease Patients with history of urinary incontinence Patients with a history of surgery on the urethra

Age
No age limit

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **172**

Randomization (investigator's opinion)
Randomized

Randomization description
The subjects were randomly divided into two groups by the method of Block Randomization

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Ethics Committee on Biological Research
Street address
Ministry of Health and Medical Education, shahrake ghods, tehran,iran
City
Tehran

Province
Tehran
Postal code
1467664961
Approval date
2018-08-04, 1397/05/13
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1397.315

Health conditions studied

1

Description of health condition studied
Urinary retention in patients undergoing anorectal surgeries
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
prevalence of urinary retention
Timepoint
The prevalence of urinary retention in the first 24 hours after surgery
Method of measurement
Urination or need of fully catheter insersion

Secondary outcomes

1

Description
Total prescribed ketorolac
Timepoint
During hospitalization
Method of measurement
Total dose of drug by mg

2

Description
Total Prescribed Pethidine
Timepoint
During Hospitalization
Method of measurement
By mg

Intervention groups

1

Description
Intervention group: In a group of patients who are in the intervention group, the patient is embedded after anorectal condom shave surgery and is evaluated for the incidence of urinary retention in the first 24 hours after the operation.

Category
Prevention

2

Description

Control group: In this group of patients after anorectal surgery, the patient is examined for urinary retention during the first 24 hours.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina Hospital
Full name of responsible person
Farzad Vaghef Davari
Street address
Sina Hospital-Imam Khomeini St.
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Tehran
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Email
Fvdavari@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr.Mohammad Ali Sahraeian
Street address
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2234557890
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Grant name

Grant code / Reference number
97-01-30-37801

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source

Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Bahare Rahmanian
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
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Sina hospital, Imam khomeini street, Tehran, Iran
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Person responsible for updating data

Contact

Name of organization / entity

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Bahare Rahmanian

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Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Postal code

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Email

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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

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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