

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Determination of Cyproterone acetate effect to prevent recurrent urinary retention in patients with Benign Prostatic Hypertrophy.

Protocol summary

Study aim

Determination of Cyproterone acetate effect to prevent recurrent urinary retention in patients with benign prostatic hypertrophy

Design

Clinical trial with control group, based on clients referred to the hospital, with groups, simple randomised, With a sample size of 84, Phase 3 Clinical Trial

Settings and conduct

A study on patients who complained of acute urinary retention to Quaem Hospital's Urology Emergency in Mashhad with a primary diagnosis of Benign Prostatic Hypertrophy. After insertion of a Urinary catheter, the patients in the intervention group are treated with cyproterone acetate and tamsulosin, and the patients in the control group are treated with thamsulosin, and then all patients are examined after one week and again one month later, followed by 6 months for second urinary retention and the need for surgical intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with acute urinary retention complaints with primary diagnosis of BPH / Exclusion criteria: prostate cancer or urinary tract infections or , sympathomimetic drugs use.

Intervention groups

Intervention group: After insertion of a Urinary catheter, patients are treated with 1mg per kg per day oral Cyproterone acetate, combined with 0.4 mg per day Tamsulosin capsule for 4 weeks. Then Tamsulosin treatment is continued for up to 6 months. The urinary catheter is removed a week after insertion. Control group: After insertion of a Urinary catheter, patients are treated with 0.4 mg per day Tamsulosin capsules for 6 months. The urinary catheter is removed a week after insertion

Main outcome variables

The main variable is the reappearance of urinary retention. Other variables that are used to diagnose urinary tract obstruction include Frequency,

intermittency, Urgency, straining, and Urinary flow force.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181106041572N1**

Registration date: **2019-04-30, 1398/02/10**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-30, 1398/02/10**

Update count: **0**

Registration date

2019-04-30, 1398/02/10

Registrant information

Name

Amin Korooji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3868 9405

Email address

karojia941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2019-05-10, 1398/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Determination of Cyproterone acetate effect to prevent recurrent urinary retention in patients with Benign Prostatic Hypertrophy.

Public title
Effect of Cyproterone acetate in patients with Benign Prostatic Hypertrophy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with acute urinary retention complaints with initial diagnosis of BPH.
Exclusion criteria:
Prostate cancer Urinary infections Use of sympathomimetic drugs

Age
From **50 years** old to **75 years** old

Gender
Male

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
Using a simple randomization method, With several envelopes are printed with the contents of the cards that are divided equally between the intervention and the control group, and People are evenly divided into two groups by shuffling and selecting the envelope. In order to hide Sealed and opaque envelopes with random sequences are used.

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

- Ethics committee of Mashhad University of Medical Sciences

Street address

Qureishi Building, Oppsite of Daneshgah 18 Ave,

Daneshgah Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

345 - 91357

Approval date

2018-10-06, 1397/07/14

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.655

Health conditions studied

1

Description of health condition studied

Benign Prostate Hypertrophy

ICD-10 code

N40

ICD-10 code description

Enlarged prostate

Primary outcomes

1

Description

urinary retention

Timepoint

checking of urinary retention immediately after removal of urinary catheter 7 days after starting of cyproterone acetate with ureteral catheter and re-examination one week and 4 weeks after it and follow up to 6 months later.

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Patients who complained of acute urinary retention are referred to the Urology Emergency Department of Quaem Hospital with primary BPH diagnosis After insertion of a Urinary catheter, are treated with 1mg per kg per day oral Cyproterone acetate, combined with 0.4 mg per day Tamsulosin capsule for 4 weeks. Then Tamsulosin treatment is continued for up to 6 months. The urinary catheter is removed a week after insertion.

Category

Treatment - Drugs

2

Description

Control group: Patients who complained of acute urinary retention are referred to the Urology Emergency Department of Quaem Hospital with primary BPH diagnosis. After insertion of a Urinary catheter, are treated with 0.4 mg per day Tamsulosin capsules for 6 months. The urinary catheter is removed a week after insertion.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Quaem hospital

Full name of responsible person

Amin Korooji

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Ahmad-abad Blvd

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99199-91766

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Quaem.Medical.Center@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahyar Mirheydari

Street address

Opposite of 18 Ave, Daneshgah Blvd

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Mirheydarim1@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Amin Korooji

Position

Medical urology assistant

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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No. 30 ,18th Ave , Fakoory Blvd , Abo-barq Town

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Amin Korooji

Position

Medical urology assistant

Latest degree

Medical doctor

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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