Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 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 Ǫuaem 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 tamsulusin, 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

Street address
Ahmad-abad Blvd

City
Mashhad

Province
Razavi Khorasan

Postal code
99199-91766

Phone
+98 51 3843 2424

Email
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

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Phone
+98 51 3845 3456

Email
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

Street address
No. 30 ,18th Ave , Fakoori Blvd , Abo-barq Town

City
Mashhad

Province
Razavi Khorasan

Postal code
9178115137

Phone
+98 51 3868 9405

Fax

Email
karojia941@mums.ac.ir

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

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Person responsible for updating data

Contact

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Mashhad University of Medical Sciences
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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