

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effect of LHRH agonist on the improvement of urinary retention compared with the effect of finasteride and tamsulosin alone

Protocol summary

Study aim

Evaluation of the synergistic effect of LHRH agonist (Leuprorelin acetate 7.5mg) with finasteride and tamsulosin on urinary retention compared with the effect of finasteride and tamsulosin on urinary retention

Design

Clinical trial with control group with randomized double blind parallel groups

Settings and conduct

Imam Reza Hospital of Mashhad . Covered packages / medications will be given to the patients according to the randomized envelope. Random numbers generated by Excel software are listed as odd / even numbers (intervention / control) and placed in separate envelopes, respectively. After opening each envelope, the nurse will, as defined by the couple or individual code, inject as prescribed or simply deliver routine medication to the patient. Also, these patients have no contact with each other and have no knowledge of each other's treatment process.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) the patient has acute urinary retention 2) is over 50 years of age. 3) first episode of urinary retention 4) no other treatment or indication of surgery 5) patient urinary retention due to BPH Exclusion criteria: a) no informed consent of the patient 2) a history of any cardiovascular and renal and metabolic diseases and seizures 3) a patient with fever mean T over 38 ° C 4) a high PSA level (above 4) suspected of having prostate cancer To strengthen.

Intervention groups

Intervention group or treatment group including group receiving routine benign prostate enlargement treatment (alpha-blocker treatment + 5 alphadectase inhibitor + LHRH agonist) Control group Benign prostate enlargement treatment group (alpha-blocker + 5-alpha reductase inhibitor)

Main outcome variables

Release from catheterization one month after acute

urinary retention

General information

Reason for update

The number of samples entered was incorrect

Acronym

IRCT registration information

IRCT registration number: **IRCT20170417033489N3**

Registration date: **2019-10-17, 1398/07/25**

Registration timing: **prospective**

Last update: **2020-02-25, 1398/12/06**

Update count: **1**

Registration date

2019-10-17, 1398/07/25

Registrant information

Name

Salman Soltani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2553

Email address

soltanis@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-22, 1398/07/30

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

2019-11-02, 1398/08/11

Actual recruitment end date

2019-12-31, 1398/10/10
Trial completion date
2020-01-30, 1398/11/10

Scientific title

The effect of LHRH agonist on the improvement of urinary retention compared with the effect of finasteride and tamsulosin alone

Public title

The effect of LHRH agonist on urinary retention

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The first acute urinary retention No other treatment No indication of surgery Patient's urinary retention is caused by BPH Minimum age of 50 years

Exclusion criteria:

Informed patient dissatisfaction History of any heart, liver, kidney, metabolic and seizure diseases Patients with fever mean T more than 38 degrees Celsius High PSA levels (above 4) which strengthen suspicion of prostate cancer

Age

From **50 years** old

Gender

Male

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **78**

Actual sample size reached: **77**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using Excel software. Random numbers are inserted in odd and even codes into the envelope, after the patient arrives at the admission criteria, and, if the patient is satisfied, the envelope is opened and will be assigned to the intervention or control group according to the patient's code. Paired and odd codes represent intervention and control groups. The codes are placed separately in the envelope so that the nurse who opens each envelope will not be aware of the allocation of the next envelope (until the next envelope is opened).

Blinding (investigator's opinion)

Double blinded

Blinding description

Evaluators and analysts will be unaware of intervention and control groups (the evaluator will only assess the extent of catheter release in the short term).

Placebo

Not used

Assignment

Parallel

Other design features

Sample size in each group was maximum predicted to be 39 people, and with predictable Decrease in the number of subjects it was 35 in each group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Qureshi building ,University Avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

99191-91778

Approval date

2019-05-07, 1398/02/17

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.512

Health conditions studied

1

Description of health condition studied

Acute urinary retention in patients with BPH

ICD-10 code

N40

ICD-10 code description

Enlarged prostate

Primary outcomes

1

Description

The rate of catheter release in acute urinary retention induced by BPH

Timepoint

One month after drug injection

Method of measurement

No need for re-catheterization

2

Description

IPSS Score

Timepoint

Before and one month after drug injection

Method of measurement

IPSS Questionnaire

3

Description

The incidence of drug side effects

Timepoint

One month after drug injection

Method of measurement

Ask the patient

4

Description

The amount of post voiding residue(PVR)

Timepoint

One day after leaving the cathedral

Method of measurement

Ultrasound

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: All patients will receive routine BPH treatment including alpha-blocker tamsulosin 0.4 mg single daily oral and alpha reductase inhibitor finasteride 5 mg single daily oral. In addition, patients in the intervention group will be given a single dose of LHRH agonist loperurelin acetate 7.5 mg at baseline.

Category

Treatment - Drugs

2

Description

Control group: All patients will receive routine BPH treatment including alpha-blocker tamsulosin 0.4 mg single daily oral and alpha reductase inhibitor finasteride 5 mg single daily oral.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Salman Soltani

Street address

Bahar Ave., Imam Reza Hospital

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<https://webda.mums.ac.ir/index.php/archive/21-daily-news/health95/medical/24594-2019-10-01-05-14-37>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Maliheh Dadgar

Street address

University street, Quarashi building

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Email

presidentoffice@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

50

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

Salman Soltani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

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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

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

Data Dictionary

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