Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Comparative study of the synergistic effect of Iso Surbide Di Nitrate on standard medical treatment in acute urinary retention compared to current standard treatment alone

Protocol summary

Study aim
Evaluation of the effect of adding ISDN to the standard treatment of acute urinary retention and comparison of the synergistic effect of this drug

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 78 patients. Sealed envelopes were used for randomization.

Settings and conduct
This study contains urology emergency department of Imam Reza (AS) and Ghaem hospitals due to acute urinary retention due to BPH. This study will be performed as randomized-clinical-trial. Eligible patients are randomly divided into two groups after obtaining conscious consent: 1 - A group that in addition to the standard treatment , 10 mg of sublingual ISDN is consumed daily for up to three weeks. 2 - Control group, which alone will be given the standard treatment Blindness will be performed for both groups of patients.

Participants/Inclusion and exclusion criteria
Entering criteria : 1) the patient has acute urinary retention 2) age more than 50 years. 3) The first episode of urinary retention 4) No other treatment or surgery indication 5) The patient's urinary retention is due to BPH The criteria for leaving the study include: 1) a history of any heart, liver, kidney, metabolic, and seizures.2) The patient has a fever of more than 38 C, 3) a high PSA (above 4) or a suspicious examination that increases the suspicion of prostate cancer. 4) Secondary urinary retention in other cases, such as neurogenic bladder

Intervention groups
The use of isosorbide dinydrate in the treatment of acute urinary retention in patients with BPH sublingually in addition to the usual standard treatments (alpha-blocker and antiandrogen) The control group will receive standard treatment

Main outcome variables
Increasing the effectiveness of drug therapy in the treatment of acute urinary retention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170417033489N5**
Registration date: **2020-05-08, 1399/02/19**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-08, 1399/02/19**
Update count: **0**

Registration date
2020-05-08, 1399/02/19

Registrant information

Name
Salman Soltani

Name of organization / entity
Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 51 3802 2553

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soltanis@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-22, 1398/03/01

Expected recruitment end date
2020-05-21, 1399/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the synergistic effect of Iso Surbide Di Nitrate on standard medical treatment in acute urinary retention compared to current standard treatment alone

Public title
Comparative study of the synergistic effect of Iso Surbide Di Nitrate on standard medical treatment in acute urinary retention compared to current standard treatment alone
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The patient has acute urinary retention He is over 50 years old. Has experienced the first episode of urinary retention Is not undergoing another treatment or has no indication for surgery The patient's urinary retention is due to the presence of BPH
Exclusion criteria:
History of any heart, liver, kidney, metabolic disease and seizures Fever in the patient means T more than 38 degrees Celsius High PSA (above 4) or suspicious examination that casts doubt on prostate cancer Secondary urinary retention in other cases such as neurogenic bladder
Age
From **50 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **78**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple individual randomization using a sealed envelope whose sequence is randomly hidden from the patient and the researcher.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants and researcher Participants are told that, in addition to standard treatment, additional treatment may be given at random, and that they will not know whether they will receive over-standard treatment.
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
Imam Reza Hospital Research Center, Mashhad, Imam Reza Square, Imam Reza Hospital
City
Mashad
Province
Razavi Khorasan
Postal code
9177899191
Approval date
2019-08-26, 1398/06/04
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1398.643

Health conditions studied

1

Description of health condition studied
BENIGN PROSTATE HYPERPLASIA
ICD-10 code
N40
ICD-10 code description
Enlarged prostate

Primary outcomes

1

Description
Percentage of patients discharged from the urinary catheter
Timepoint
21 DAYS
Method of measurement
Lack of urinary retention following urinary catheter removal

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to standard alpha-blocker (capsule Tamsulosin 0.4 mg Daily) and antiandrogen (tablet Finastride 5 mg Daily)therapyy, 10 mg of

isosorbide dinitrate is used sublingualy daily for up to three weeks.

Category

Treatment - Drugs

2

Description

Control group: A group receiving standard alpha-blocker (capsule Tamsulosin 0.4 mg Daily) and antiandrogen (tablet Finastride 5 mg Daily)therapy

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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webda@mums.ac.ir

Web page address

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

Dr Mahmood Tavakkoli

Street address

Daneshgah Avenue

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Web page address

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

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

Salman Soltani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Specialist
Other areas of specialty/work
Urology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All collected deidentified IPD
When the data will become available and for how long
starting 6 months after publication
To whom data/document is available
Access to data will be unlimited
Under which criteria data/document could be used
Requesting data will be unlimited
From where data/document is obtainable
Dr. Salman Soltani. Urology Department of Imam Reza Hospital. Mashhad. Iran Phone +98 51 3871 3638
What processes are involved for a request to access data/document
After submitting the application, the information will be provided to the applicant as soon as possible
Comments