

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 dinitrate 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)

Phone

+98 51 3802 2553

Email address

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 sublingually 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

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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

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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Full name of responsible person

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Person responsible for updating data

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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