Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Compare the effect of extended-release toltoredine and solifenacin in the treatment of urinary frequency and nocturia in overactive bladder symptoms patients.

Protocol summary

Summary

The purpose of this study is the comparison between the two drugs of Detrozitol and Sulfiniyacin. So , to help the appropriate prescribing drug to patients with overactive bladder. In this study, women with overactive bladder referring to Imam Khomeini hospital after history taking and physical examination by Using the urine three-day chart and questionnaire are checked. Women Age more than 18 years of age, incontinence urgency, urinary frequency more than 8 times at a day and more than once at night or sense of urgency to urinate in 24 hours were the inclusion criteria's. Then, the 100 patients were enrolled by using a table of random numbers and are placed in one of the groups receiving the drug of Detrozitol(n=50) and Sulfiniyacin(n=50). The drugs were excluded of Blister and were placed ina paper bags withouta name and with a code. The questioning, the patient and the analyst were blinded to it. Only someone who has been encoded was aware of the contents of the envelope. In both groups, the patients use of drug, once a day and orally for 8 weeks, and again at the end of the treatment, the questionnaire, physical examination, and the patient's chart were assesed. The primary outcomes were the effects of the two drugs on symptoms of overactive bladder (Urine frequency, Nucturia) and the secondary outcome was the drug side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101727998N3**
Registration date: **2017-06-10, 1396/03/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-10, 1396/03/20

Registrant information

Name

Maryam Hajihashemi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3776 6578

Email address

m_hajihashemy@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-Chancellor of Tehran University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of extended-release toltoredine and solifenacin in the treatment of urinary frequency and nocturia in overactive bladder symptoms patients.

Public title

Compare the effect of Tetoltoredine and solifenacin in treatment of over active bladder symptoms.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Age more than 18 years; Urge incontinence; Mixed incontinence; urination in the day more than 8 times and urination in the night more than once; more than once a day with urge incontinence; Sense of urgency to urinate in 24 hours. Exclusion Criteria: Lack of consent to the participation; Contraindications received antimuscarinic drugs such as glaucoma.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Tehran University of MedicaLSciences.

Street address

Central Building of Vice Chancellor of Tehran University of Medical sciences، Ghods Street, Tehran.

City

Tehran

Postal code

14194

Approval date

2017-03-15, 1395/12/25

Ethics committee reference number

IR.TUMS.VCR.REC.1395.1977

Health conditions studied

1

Description of health condition studied

stress incontinance

ICD-10 code

N39.3

ICD-10 code description

stress incontinance

Primary outcomes

1

Description

urinary frequency

Timepoint

Before and two month after treatment.

Method of measurement

Specific Questionaire

2

Description

Nuctury (frequency of night urination)

Timepoint

Before and two month after treatment.

Method of measurement

Specific Questionaire

Secondary outcomes

1

Description

Drug complication

Timepoint

two month after treatment

Method of measurement

Ask the patient

Intervention groups

1

Description

Intervention group 1: The orally sustained release drug of Tuliridin (Detrozitol) 4 mg a day (once a day) for two months.

Category

Treatment - Drugs

2

Description

Intervention group 2: The oral drug of ٔSulfiniacin ,4 mg a day (once a day) for two months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Vali Asr Pelvic Clinic
Full name of responsible person
Dr.Maryam Hajhashemy
Street address
Valiasr Pelvic Clinic، Imam Khomeini Hospital، Keshavarz Blvd.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Tehran University of Medical Sciences
Full name of responsible person
Dr.Masoud Younesian
Street address
Floor N.6, Central Bulding , Ghods Street.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Pelvic Clinic of Valiasr Hospital
Full name of responsible person
Dr.Maryam Hajhashemy
Position
Pelvic Flowship
Other areas of specialty/work
Street address
Fifth floor,Valiasr Hospital number1,Imam Khomeini Hospital,Keshavarz Blvd.
City
Tehran
Postal code
14194
Phone
+98 21 6119 2363
Fax
Email
hajhashemy73@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Reproductive Health Research Center
Full name of responsible person
Dr.Zinat Ghanbari
Position
Professor
Other areas of specialty/work
Street address
First floor,Valiasr Hospital 2,Imam Khomeini Hospital,Keshavarz Blvd
City
Tehran
Postal code
14194
Phone
+98 21 6658 1616
Fax
+98 21 6658 1658
Email
drz_ghanbari@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Vali Asr Reproductive Health Research Center
Full name of responsible person
Fedyeh Haghollahi
Position
Expert in Research
Other areas of specialty/work
Street address
First floor,Valiasr Hospital 2,Imam Khomeini Hospital,Keshavarz Blvd.
City
Tehran
Postal code
14194
Phone
+98 21 6658 1616
Fax
+98 21 6658 1658
Email
fedyeh_hagh@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty