

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

**Compare the effect of extended-release tolterodine 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 Detrol and Sulfiniacin. 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 Detrol(n=50) and Sulfiniacin(n=50). The drugs were excluded of Blister and were placed in a paper bag without a 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 assessed. The primary outcomes were the effects of the two drugs on symptoms of overactive bladder (Urine frequency, Nocturia) 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 Hajhashemi

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

m\_hajhashemy@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 tolterodine and solifenacin in the treatment of urinary frequency and nocturia in overactive bladder symptoms patients.

#### Public title

Compare the effect of Tolterodine 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 Medical Sciences.

##### **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**

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**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**

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**Web page address****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****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

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**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*