

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Comparison of the effect of tamsulosin and tadalafil in response to treatment of patients with lower urinary tract symptoms due to the severity of atherosclerosis

#### Protocol summary

##### Study aim

effect of atherosclerosis on the efficacy of tamsulosin and tadalafil in male patients with urinary obstructive symptoms

##### Design

A clinical trial with two groups of patients: parallel, therapeutic, simple random

##### Settings and conduct

Based on Framingham criteria, each person referred to Sina Hospital is rated based on age, serum cholesterol level, serum level, HDL smoking, and systolic blood pressure. Patients are divided into two groups with a high risk of coronary artery disease and low to moderate risk of coronary artery disease. In each group, patients are divided into two groups. In one group treatment with tamsulosin 0.4 mg daily and in the other group treatment with tadalafil 5 mg and tamsulosin 0.4 mg daily. Patients were evaluated for PVR, IPSS, IPSS-QOL, and IIEF-5 before, 4, 8, and 12 weeks after treatment. Q max is assessed before treatment and after 12 weeks. The data will be analyzed using spss22 software. A comparison of quantitative variables in the study with the T-test and comparison of qualitative variables with the Chi-square test is performed and in cases where the distribution of data is not normal by non-parametric tests Used.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: Male patients referred to urology clinic with obstructive and urinary tract symptoms for at least 6 months Patients over 50 years of age Exclusion criteria: Cardiovascular diseases such as significant angina that need to be checked by a cardiologist and CHF not compensated, recent MI and uncontrolled blood pressure treatment with nitrates

##### Intervention groups

Intervention group1: Treatment with tamsulosin 0.4 mg daily Intervention group2: Treatment with tadalafil 5 mg

+tamsulosin 0.4 mg daily

##### Main outcome variables

Effective treatments for obstructive and urinary tract symptoms in patients

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191230045943N1**

Registration date: **2020-10-03, 1399/07/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-10-03, 1399/07/12**

Update count: **0**

##### Registration date

2020-10-03, 1399/07/12

##### Registrant information

##### Name

Ali Tavoosian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6634 8561

##### Email address

alitavoosian@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-30, 1399/07/09

##### Expected recruitment end date

2021-05-30, 1400/03/09

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of tamsulosin and tadalafil in response to treatment of patients with lower urinary tract symptoms due to the severity of atherosclerosis

**Public title**  
the effect of tamsulosin and tadalafil in response to treatment of patients with lower urinary tract symptoms

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Male patients referred to urology clinic with obstructive and urinary tract symptoms for at least 6 months  
Patients over 50 years of age  
**Exclusion criteria:**  
Male patients referred to urology clinic less than 50 years old PSA higher than 10 Urine residue 300ml or higher determined by ultrasound Receiving Finasteride during the last 3 months Receiving anti-androgen drugs History of pelvic surgery or radiotherapy History of lower urinary tract malignancy Lower urinary tract trauma Urinary retention Bladder stones Urinary tract infection that is determined by urine culture Urethral stricture Neurological disease affecting bladder function Secondary obstruction to the median lobe of the prostate Prostate cancer Liver or kidney failure Cardiovascular diseases such as significant angina that need to be checked by a cardiologist and CHF not compensated, recent MI and uncontrolled blood pressure treatment with nitrates Uncontrolled diabetes HbA1c > 9%

**Age**  
From **50 years** old to **100 years** old

**Gender**  
Male

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **200**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The randomization method used will be simple randomization. And the random number table will be used. If a number is randomly selected we will move to the right according to the present contract and if the number even comes in The patient will be admitted to the intervention group and if the number comes in, the patient will be included in the second group. (Assigning patients based on the severity of atherosclerosis in two general categories of low severity and high severity of atherosclerosis based on the couple and individual referral number)

**Blinding (investigator's opinion)**

Not 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 for Research in Tehran University of Medical Sciences

##### Street address

Room 604, Sixth Floor, medical University Tehran, Central Staff Building, Keshavarz Blvd., Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

#### Approval date

2020-09-30, 1399/07/09

#### Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1399.042

## Health conditions studied

### 1

#### Description of health condition studied

Atherosclerosis

#### ICD-10 code

I70

#### ICD-10 code description

Atherosclerosis

### 2

#### Description of health condition studied

Obstructive and urinary tract symptoms

#### ICD-10 code

N13.9

#### ICD-10 code description

Obstructive and reflux uropathy, unspecified

## Primary outcomes

### 1

#### Description

Treatment of obstructive and urinary tract symptoms

#### Timepoint

At one month intervals for three months

#### Method of measurement

Q max evaluation

#### Secondary outcomes

empty

#### Intervention groups

##### 1

#### Description

Intervention group: Treatment with tamsulosin 0.4 mg daily one alone- (Trade names, Flomax, others )- Patients before treatment, 4, 8 and 12 weeks after starting treatment (PVR, IPSS, IPSS-QOL and IIEF-5) are evaluated. Q max is assessed before starting treatment and after 12 weeks.

#### Category

Treatment - Drugs

##### 2

#### Description

Intervention group: Treatment with tadalafil 5 mg+tamsulosin 0.4 mg once daily - Patients before treatment, 4, 8 and 12 weeks after starting treatment (PVR, IPSS, IPSS-QOL and IIEF-5) are evaluated. Q max is assessed before starting treatment and after 12 weeks.

#### Category

Treatment - Drugs

#### Recruitment centers

##### 1

#### Recruitment center

##### Name of recruitment center

Sina hospital

##### Full name of responsible person

Dr Ali Tavoosian

##### Street address

Hassan Abad street

##### City

Tehran

##### Province

Tehran

##### Postal code

1136746911

##### Phone

+98 21 6634 8500

##### Fax

+98 21 6634 8553

##### Email

alitavoosian@tums.ac.ir

##### Web page address

<http://urc.tums.ac.ir>

#### Sponsors / Funding sources

##### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Ali Sahraian

##### Street address

Tehran. Keshavarz Boulevard, Quds Ave., Central University, Sixth Floor

##### City

Tehran

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##### Postal code

1417653761

##### Phone

+98 21 8163 3685

##### Fax

+98 21 8163 3686

##### Email

vcr@tums.ac.ir

##### Web page address

<http://vcr.tums.ac.ir/>

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Tehran 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

Tehran University of Medical Sciences

##### Full name of responsible person

Dr Akram Mirzaei

##### Position

Researcher

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Molecular Medicine

##### Street address

Urology Research Center- Sina Hospital - Imam Khomeini St

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**Email**

mirzaee.scholar@gmail.com

**Web page address**<https://URC@tums.ac.ir>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Ali Tavoosian

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Urology

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Urology Research Center- Sina Hospital - Imam Khomeini St

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**Web page address**<http://urc.tums.ac.ir>**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Akram Mirzaei

**Position**

Researcher

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Molecular Medicine

**Street address**

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+98 21 6634 8561

**Email**

mirzaee.scholar@gmail.com

**Web page address**<https://URC@tums.ac.ir>**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**

No - There is not a plan to make this available

**Data Dictionary**

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

**Title and more details about the data/document**

demographic information anonymously

**When the data will become available and for how long**

one year after publication

**To whom data/document is available**

register

**Under which criteria data/document could be used**

Re-information for the purpose of clarification

**From where data/document is obtainable**

Dr. Ali Tavoosian

**What processes are involved for a request to access data/document**

After the examination, the applicant will be provided with the advice of an epidemiologist and with the confidentiality of patient information.

**Comments**

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