Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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+98 21 6634 8561

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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 HbAlc> 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraian

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

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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

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Person responsible for scientific inquiries

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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
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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