Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison the effect of tadalafil 20 mg alone and tadalafil 5 mg with tamsulosin on erectile dysfunction in diabetic patients

Protocol summary

Study aim

Comparison The effect of tadalafil 20 mg alone and tadalafil 5 mg with tamsulosin on erectile dysfunction in diabetic patients

Design

Clinical trial with a control group, with parallel groups, phase 3 on 154 patients. The rand function of Excel software was used for randomization.

Settings and conduct

In this clinical trial study, all patients with diabetes who are treated with symptoms of lower urinary system and erectile dysfunction in Shahid Beheshti Hospital of Babol are included in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria included known cases of diabetes with symptoms of the lower urinary system and erectile dysfunction aged between 50-70 years with IPSS greater than 12 who are treated with oral diabetes medications or insulin. Exclusion criteria include uncontrolled blood pressure, chronic kidney disease, liver failure, unstable coronary disease, psychiatric disease, contraindications to receiving tadalafil or tamsulosin, prostate malignancies, bladder stones, history of retention, history of previous prostate surgery, urinary system infection, neurogenic bladder, treatment with finasteride in the last 6 months, history of urethral stricture, and history of bladder neck obstruction.

Intervention groups

Intervention group: tadalafil 20 mg tablet(Farabi, Iran) one tablet daily for 4 weeks and control group treatment with tamsulosin 0.4 mg (Farabi, Iran) with tadalafil 5 mg (Aria, Iran) once daily for 4 weeks. In both groups of patients, before treatment, 4, 8 and 12 weeks after the treatment, the international score of prostate symptoms and the international index of erectile function are evaluated. Q max is evaluated before treatment and after 12 weeks.

Main outcome variables

Sexual function, lower urinary tract symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221127056624N2**
Registration date: **2023-05-10, 1402/02/20**
Registration timing: **retrospective**

Last update: **2023-05-10, 1402/02/20**
Update count: **0**

Registration date

2023-05-10, 1402/02/20

Registrant information

Name

Abazar Akbarzadeh pasha

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 11 3222 6285

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-16, 1400/04/25

Expected recruitment end date

2021-09-16, 1400/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of tadalafil 20 mg alone and tadalafil 5 mg with tamsulosin on erectile dysfunction in diabetic patients

Public title
The effect of tadalafil alone and tadalafil with tamsulosin in sexual dysfunction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Known cases of diabetes with lower urinary tract symptoms and erectile dysfunction Age between 50-70 years With international prostate symptom score greater than 12 in who are treated with oral diabetes medications or insulin
Exclusion criteria:
Uncontrolled blood pressure Chronic kidney disease Liver failure Unstable coronary disease Psychiatric illness Contraindications to receiving tadalafil or tamsulosin Prostate malignancies bladder stones Retention history History of previous prostate surgery Urinary tract infection Neurogenic Bladder Treatment with finasteride in the last 6 months History of ductal stenosis History of bladder neck obstruction
Age
From **50 years** old to **70 years** old
Gender
Male

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **154**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of allocating the subjects after applying the inclusion and exclusion criteria will be random allocation in the block method. The randomization unit is an individual. The size of the blocks is 4 and in each block each intervention group will be repeated twice. Then using Excel 2016 software, a sequence of size 154 will be produced. Using this randomly generated list, the participants are assigned to one of the two study groups. In order to hide the list of random allocation, a special code will be assigned to each of the intervention groups, which only the main executor of the project (supervisor) will be aware of.
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 of Babol University of Medical Sciences
Street address
Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran
City
Babol
Province
Mazandaran
Postal code
4716681451
Approval date
2021-06-15, 1400/03/25
Ethics committee reference number
IR.MUBABOL.REC.1400.161

Health conditions studied

1

Description of health condition studied
Erectile Dysfunction
ICD-10 code
N51
ICD-10 code description
Disorders of male genital organs in diseases classified elsewhere

Primary outcomes

1

Description
Erectile Dysfunction
Timepoint
Before intervention, 4, 8 and 12 weeks after intervention
Method of measurement
The International Index of Erectile Function (IIEF)

Secondary outcomes

1

Description
Lower urinary tract symptoms
Timepoint
Before intervention, 4, 8 and 12 weeks after intervention
Method of measurement
The International Prostate Symptom Score (IPSS)

Intervention groups

1

Description

Intervention group: Tadalafil 20 mg tablets(Farabi, Iran), one tablet daily for 4 weeks. Patients were evaluated before treatment, 4, 8, and 12 weeks after treatment by International Prostate Symptom Score and International Index of Erectile Function. Q max is evaluated before treatment and after 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: Treatment with tamsulosin 0.4 mg(Farabi, Iran) with tadalafil 5 mg(Aria, Iran) once a day for 4 weeks. Patients are evaluated before treatment, 4, 8 and 12 weeks after treatment by international score of prostate symptoms and international index of erectile function. Q max is evaluated before treatment and after 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr. Abazar akbarzadeh Pasha

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Babol Shahid Beheshti Hospital, Shahid Ghasemi Street, Babol, Mazandaran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Mehdi Rajabnia

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Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Seyyed Hossein Ghasemi

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

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Specialist
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Person responsible for updating data

Contact
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Dr. Abazar Akbarzadeh Pasha
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Latest degree
Specialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available