

# 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)

##### Phone

+98 11 3222 6285

##### Email address

a.pasha@mubabol.ac.ir

##### 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

##### Street address

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

##### City

Babol

##### Province

Mazandaran

##### Postal code

4716681451

##### Phone

+98 11 3225 2071

##### Email

beheshti@mubabol.ac.ir

##### Web page address

<http://www.mubabol.ac.ir/>

## Sponsors / Funding sources

## 1

#### Sponsor

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Dr. Mehdi Rajabnia

##### Street address

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

##### City

Babol

##### Province

Mazandaran

##### Postal code

4716681451

##### Phone

+98 11 3219 7667

##### Email

ramazan@yahoo.com

##### Web page address

<http://www.mubabol.ac.ir/>

#### 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

##### Street address

Babol University of Medical Sciences; Ganjafrooz Street; Babol; Iran

##### City

Babol

##### Province

Mazandaran

##### Postal code

4716681451

##### Phone

+98 11 3225 6285

##### Email

ghosein591@gmail.com

##### Web page address

<http://www.mubabol.ac.ir/>

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Abazar Akbarzadeh Pasha

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Urology

**Street address**

Babol University of Medical Sciences; Ganjafrooz Street; Babol; Iran

**City**

Babol

**Province**

Mazandaran

**Postal code**

4716681451

**Phone**

+98 11 3225 6285

**Email**

a.pasha@mubabol.ac.ir

**Web page address**

<http://www.mubabol.ac.ir/>

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Abazar Akbarzadeh Pasha

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Urology

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+98 11 3225 6285

**Email**

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**Web page address**

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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