

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Effects of Testosterone Therapy on Erectile Dysfunction in Type 2 Diabetes Mellitus Patients with normal level of Testosterone

Protocol summary

Study aim

Effects of Testosterone in the treatment of erectile dysfunction in patients with type 2 diabetes mellitus

Design

Clinical trial, Superiority, Single blind, Two-arm parallel group, Per-protocol

Settings and conduct

Type 2 diabetes mellitus Patients with erectile dysfunction who referred to urology clinic of Ghaem or Emam Reza hospitals, affiliated to Mashhad university of medical sciences, were enrolled in this study. The baseline level of testosterone was normal in all participants. Before the study commencement laboratory parameters including liver function tests, CBC, PSA, and lipid profile were measured for all participants. Patients were excluded if they had any contraindication for testosterone or Tadalafil consumption. We used closed pockets for allocation concealment. IIEF-5 questionnaire was completed by blind evaluators at baseline, 3-month and 6-month follow-up. After 3-month the laboratory tests were measured again.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Completing the written informed consent Presence of Erectile dysfunction Presence of Type 2 Diabetes Mellitus Normal Serum Testosterone level IIEF= $\leq$ 16 Exclusion criteria: Contraindication for Tadalafil consumption including Heart disease, Hypertension, and Nitrocontin consumption Contraindication for Tadalafil consumption including liver disorder and prostate cancer

Intervention groups

Intervention group: Administration of 250mg Testosterone at study commencement and the first and second month of the study+standard treatment using 20mg Tadalafil 2-hour before intercourse. Control group: standard treatment using 20mg Tadalafil 2-hour before intercourse

Main outcome variables

IIEF-5 score Lipid profile CBC PSA Liver Function test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181106041575N1**

Registration date: **2019-05-17, 1398/02/27**

Registration timing: **retrospective**

Last update: **2019-05-17, 1398/02/27**

Update count: **0**

Registration date

2019-05-17, 1398/02/27

Registrant information

Name

Esmail Tootoonchi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3843 2857

Email address

totonchie951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-04-04, 1398/01/15

Actual recruitment start date

2018-10-23, 1397/08/01

Actual recruitment end date

2019-04-04, 1398/01/15

Trial completion date

2019-04-14, 1398/01/25

Scientific title

Effects of Testosterone Therapy on Erectile Dysfunction in Type 2 Diabetes Mellitus Patients with normal level of Testosterone

Public title
Testosterone Therapy in Type 2 Diabetes Mellitus Patients with Erectile Dysfunction

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Presence of Erectile dysfunction Presence of Type 2 Diabetes Mellitus Normal Serum Testosterone level IIEF=<16
Exclusion criteria:
Contraindication for Tadalafil consumption including: Heart disease, Hypertension and Nitrocontin consumption Contraindication for Tadalafil consumption including: liver disorder and prostate cancer

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **66**
Actual sample size reached: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
This study used simple randomization. Randomization units consisted of individuals. We used closed pockets for randomization.

Blinding (investigator's opinion)
Single blinded

Blinding description
Study participants: patients will be divided into intervention and control groups. control and the intervention group won't notice the treatment protocols in other group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees
1
Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
No. 18, Daneshgah Ave, Mashhad, Iran.
City
Mashhad
Province
Razavi Khorasan
Postal code
91388-13944
Approval date
2018-10-16, 1397/07/24
Ethics committee reference number
ir.mums.medical.rec.1397.352

Health conditions studied

1

Description of health condition studied

Erectile dysfunction

ICD-10 code

F52.21

ICD-10 code description

Male erectile disorder

Primary outcomes

1

Description

erectile dysfunction according to The International Index of Erectile Function (IIEF-5).

Timepoint

International Index of Erectile Function (IIEF-5) was completed before, 3-month, and 6-month after the intervention

Method of measurement

erectile dysfunction according to The International Index of Erectile Function (IIEF-5).

Secondary outcomes

1

Description

the side-effects of the intervention

Timepoint

before and 3-month after the intervention

Method of measurement

the side-effects of the intervention was measured using laboratory findings including liver function test, complete blood count (CBC), liver function test (LFT), fasting blood sugar and Prostate-specific antigen (PSA).

Intervention groups

1

Description

Intervention group: intramuscular injection of 250 mg testosterone each month for 3 consecutive months in addition of 20mg Tadalafil, 2-hour before each

intercourse.

Category

Treatment - Drugs

2

Description

Control group: oral consumption of 20mg Tadalafil, 2-hour before each intercourse.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Urology clinic of Ghaem hospital

Full name of responsible person

Salman Soltani

Street address

Parastar Ave, Ahmad Abad blvd

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91766-99199

Phone

+98 51 3840 0000

Email

Quaem.Medical.Center@mums.ac.ir

2

Recruitment center

Name of recruitment center

Urology clinic of Emam Reza hospital

Full name of responsible person

Salman Soltani

Street address

Emam Reza square

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Province

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9137913316

Phone

+98 51 3854 3031

Email

emamreza@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research and technology deputy of Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Ghoreishi building, Daneshgah Ave.

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Province

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Postal code

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Phone

+98 51 3841 2081

Email

TafaghodiM@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research and technology deputy of Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Esmail Totonchi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Salman Soltani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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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

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

Analytic Code

Yes - There is 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

these files will be presented upon request: Patients` data after removing their identity, Research protocol, statistical methods used in this study and written informed consent.

When the data will become available and for how long

data will be available 3 months after the article has been published

To whom data/document is available

Any researcher who needs our data to accomplish his research

Under which criteria data/document could be used

The researcher should use these data only in their related research and should mention the reference

From where data/document is obtainable

Researchers should send their request to Dr. Salman Soltani via email. Email:SoltaniS@mums.ac.ir

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

Researchers should send their request for data that includes their reasons for using the data and their study protocols and aims. The request will be answered during 14 business days

Comments

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Esmaeil Totonchi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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