

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Evaluation of the role of Atorvastatin to improve the response to Sildenafil in men with erectile dysfunction without response to Sildenafil alone

Protocol summary

Summary

Our goal is assessing the effect of Atorvastatin in responding to Sildenafil in those patients with erectile dysfunction and no previous good response to Sildenafil. Inclusion criteria include presence of erectile dysfunction without a proper response to the Sildenafil treatment. Exclusion criteria include Nitrate users; presence of high serum lipids, diabetes mellitus, thyroid disease, mental disorder, liver disease and Renal failure. We study patients who were visited at heart or urology clinics in Moddares Hospital for their erectile dysfunction. Our study is a randomized double-blind placebo controlled trial and we are going to study 152 patients with erectile dysfunction. We will divide patients into two intervention and control groups. Then, patients will be treated with Sildenafil 100mg and Atorvastatin 40 mg before every intercourse in intervention group and Sildenafil 100 mg and placebo in control group. Patients will be assessed by IIEF-5 and GEQ questionnaires, 6 and 12 weeks after the treatment and two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138802301267N3**

Registration date: **2009-08-03, 1388/05/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2009-08-03, 1388/05/12

Registrant information

Name

Mojgan Borgheie

Name of organization / entity

Urology and Nephrology Research Center (UNRC),
Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Urology and Nephrology Research Center (UNRC),
Shahid Beheshti University, M.C.(SBMU), Tehran, I.R.
Iran

Expected recruitment start date

2009-06-22, 1388/04/01

Expected recruitment end date

2009-12-22, 1388/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the role of Atorvastatin to improve the response to Sildenafil in men with erectile dysfunction without response to Sildenafil alone

Public title

Evaluation of the role of Atorvastatin to improve the response to Sildenafil in men with erectile dysfunction without response to Sildenafil alone

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Presence of erectile dysfunction and without a proper response to the Sildenafil treatment,
 Exclusion criteria: Receiving nitrate drugs, high serum lipids (LDL>130, Cholesterol >200), Receiving Statin drugs, Acute coronary accidents in the 6 month prior to study, severe and uncontrolled diabetes mellitus, active thyroid disease, mental disorder or depression diagnosed by a psychiatrist, prostate surgery history with the consequent ED, active liver disease, renal failure (cr>2)

Age
 No age limit

Gender
 Male

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **152**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Double blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

1

Registry name
Secondary trial Id
Registration date
 2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee
Name of ethics committee
 Urology and Nephrology Research Center (UNRC),
 Shahid Beheshti University, M.C.(SBMU), Tehran, I.

Street address
 UNRC, No.101, Boostan 9th St., Pasdaran Ave.,
 Tehran, I.R. Iran

City
 Tehran

Postal code
 1666677951

Approval date
 empty

Ethics committee reference number
 93

Health conditions studied

1

Description of health condition studied
 Erectile dysfunction

ICD-10 code
 N48.4

ICD-10 code description
 Impotence of organic origin

Primary outcomes

1

Description
 Erectile dysfunction

Timepoint
 Baseline and 6 and 12 weeks after treatment

Method of measurement
 IIEF-5 questionnaire

Secondary outcomes

1

Description
 Sexual ability

Timepoint
 Baseline and 6 and 12 weeks after treatment

Method of measurement
 IIEF-5 , GEQ questionnaire

Intervention groups

1

Description
 Atorvastatin 40 mg/day and Sildenafil 100 mg before every intercourse

Category
 Treatment - Drugs

2

Description
 Placebo with the same dose and shaoe as Atorvastatin and Sildenafil 100 mg before every intercourse

Category
 Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
 Moddares Hospital

Full name of responsible person
Street address
City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urology and Nephrology Research Center (UNRC),
Shahid Beheshti University, M.C.(SBMU), Tehran

Full name of responsible person

Shabnam Golshan

Street address

UNRC, No.101, Boostan 9th St., Pasdaran Ave.,
Tehran, I.R. Iran

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Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Urology and Nephrology Research Center (UNRC),
Shahid Beheshti University, M.C.(SBMU), Tehran

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Urology and Nephrology Research Center (UNRC),
Shahid Beheshti University, M.C.(SBMU), Tehran, I.R

Full name of responsible person

Dr Alireza Lasheie

Position

Resident of Urology

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Position

Professor

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Person responsible for updating data

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Full name of responsible person

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Position

General Physician

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty
Informed Consent Form
empty
Clinical Study Report
empty

Analytic Code
empty
Data Dictionary
empty