Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 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 Mediacal Sciences

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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, Cholestrol >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.

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

City
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Postal code
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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 و 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
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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
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

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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