

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 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)

##### Phone

+98 21 2256 7222

##### Email address

research@unrc.ir

##### 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

**City**

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

**Other areas of specialty/work****Street address**

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

**City**

Tehran

**Postal code**

1666677951

**Phone**

+98 21 22567222

**Fax**

+98 21 77954

**Email**

Research@unrc.ir

**Web page address**

www.unrc.ir

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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

**Full name of responsible person**

Dr Farid Dadkhah

**Position**

Professor

**Other areas of specialty/work****Street address**

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

**City**

Tehran

**Postal code**

1666677951

**Phone**

+98 21 2256 7222

**Fax**

+98 212277954

**Email**

Research@unrc.ir

**Web page address**

www.unrc.ir

## Person responsible for updating data

**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 Mozghan Borgheie

**Position**

General Physician

**Other areas of specialty/work****Street address**

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

**City**

Tehran

**Postal code**

1666677951

**Phone**

+98 21 2256 7222

**Fax**

+98 212277954

**Email**

borgheie@unrc.ir

**Web page address**

www.unrc.ir

## 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*