

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Effect of Vaginal Sildenafil on Female Sexual Function Index and Sexual Satisfaction, in Premenopause and Postmenopause Women

#### Protocol summary

##### Summary

Objective: Sexual dysfunction is one of the most common problems of women in all age groups, cultural and socioeconomic groups. Menopause and estrogen reductions in the body increase the perceived severity of sexual problems. Sexual dysfunction affects not only personal and marital relationships, but also the quality of sexual life of individuals. Design: This is a double-blind clinical trial. Participants: 100 postmenopausal women and 100 non-menopausal women aged 45-65 and postmenopausal 25-45 years old in Tehran. Setting and conduct: Participants were randomly divided into two groups of drug users and placebo for three months. The instrument used in this study is Gender Equity Standards and Sexual Function Index of Women that is completed and reviewed before and three months after drug intake. Intervention: 100 mg sildenafil tablets and placebo are taken vaginally 1 hour before each sexual intercourse for 3 months. Main outcome measure: Improving female sexual satisfaction and sexual function is the main outcome variable.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013112015461N1**

Registration date: **2017-11-07, 1396/08/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-11-07, 1396/08/16

##### Registrant information

##### Name

Azar Mashhoori Vayghan

##### Name of organization / entity

Tarbiat Modares University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6641 5778

##### Email address

azar.mashhoori@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator

##### Expected recruitment start date

2015-06-22, 1394/04/01

##### Expected recruitment end date

2016-10-22, 1395/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Vaginal Sildenafil on Female Sexual Function Index and Sexual Satisfaction, in Premenopause and Postmenopause Women

##### Public title

Effect of Vaginal Sildenafil on Female Sexual Function Index and Sexual Satisfaction

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 45-65 years old in post menopause and 25-45 years old in premenstrual women; Being sexually active; at least 12 month amenorrh in post menopause women; no surgical menopause; no hormone replacement therapy; BMI= 19.8-30; no high BP; no drug use; no smoking; no alcohol; no liver; heart; thyroid

disease or diabetic; no chronic disease; no cancer or precancerous disease; no vaginal bleeding; no endometrial hyperplasia or polyp; no pelvic radiation.

#### Age

From **25 years** old to **65 years** old

#### Gender

Female

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **100**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

nothing

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tarbiat Modarres University

##### Street address

Nasr bridge, Jalale Ale Ahmad.

##### City

Tehran

##### Postal code

14445-331

#### Approval date

2013-12-11, 1392/09/20

#### Ethics committee reference number

552/4999

## Health conditions studied

### 1

#### Description of health condition studied

Female Sexual Dysfunction and Satisfaction

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Improvement of female sexual satisfaction and sexual function

#### Timepoint

Three months after the intervention

#### Method of measurement

Complete Sexual Function Questionnaire (FSFI) and Sexual Satisfaction (ISS) before and after intervention

## Secondary outcomes

### 1

#### Description

Effect on Endometrial Thickening and Intraepithelial Maturation Index in Menopause Women

#### Timepoint

Three Months after the Intervention

#### Method of measurement

Vaginal Sonography and Pap smear

## Intervention groups

### 1

#### Description

Taking 100 mg sildenafil tablets 1 hour before each vaginal intercourse for 3 months

#### Category

Treatment - Drugs

### 2

#### Description

Taking sildenafil tablets 1 hour before sexual intercourse for 3 months

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Gynecology office

##### Full name of responsible person

Dr Zohre Shahverdi

##### Street address

No. 390, St. Eight, North Mofat, Shahid Beheshti Street.

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

Name of organization / entity

Vice chancellor for research, Tarbiyat Modares  
Univercity

**Full name of responsible person**

Dr. Saeideh Ziaei

**Street address**

Tarbiyat Modares Univercity, Jalal Al Ahmad, Tehran,  
Iran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research, Tarbiyat Modares Univercity

**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**

Tarbiat Modares Univercity

**Full name of responsible person**

Azar Mashhoori Vayghan

**Position**

Master student of midwifery

**Other areas of specialty/work**

**Street address**

No 2, Hadaf, Shahid sokhanvar, Valiasr.

**City**

Tehran

**Postal code**

1137613616

**Phone**

+98 21 6641 5778

**Fax**

**Email**

azar.mashhoori@modares.ac.ir,

azar.mashhoory@gmail.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tarbiat Modares Univercity

**Full name of responsible person**

Azar Mashhoori Vayghan

**Position**

Midwifery/ MSC

**Other areas of specialty/work**

**Street address**

No 2, Hadaf, Shahid sokhanvar, Valiasr.

**City**

Tehran

**Postal code**

113761316

**Phone**

+98 21 6641 5778

**Fax**

**Email**

azar.mashhoori@modares.ac.ir,

azar.mashhoory@gmail.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Modares univercity

**Full name of responsible person**

Azar Mashhoori Vayghan

**Position**

Master student

**Other areas of specialty/work**

**Street address**

No 2, Hadaf, Shahid Sokhanvar, Valiasr.

**City**

Tehran

**Postal code**

1137613616

**Phone**

+98 21 6641 5778

**Fax**

**Email**

azar.mashhoori@modares.ac.ir,

azar.mashhoory@gmail.com

**Web page address**

## 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*