Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 post-menopausal 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

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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 amenorah 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 Interaepitelial 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

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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