

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Evaluation of the effect of sildenafil along with melatonin on the sexual function of patients with polycystic ovary syndrome treated with metformin.

Protocol summary

Study aim

Evaluation of the effect of sildenafil along with melatonin on the sexual function of patients with polycystic ovary syndrome treated with metformin.

Design

clinical trial with a control group; with parallel groups; Randomized; Designed in 216 patients

Settings and conduct

Eligible patients referred to Shahid Muftah Clinic of Yasouj University of Medical Sciences will be divided into four groups of 54 people and sexual performance will be measured.

Participants/Inclusion and exclusion criteria

Eligibility conditions: patients aged 18 to 45 years; body mass index 19-25; Confirmation of polycystic ovary syndrome based on the Rotterdam criteria. Conditions for not entering the study: patients who do not want to cooperate; Sildenafil sensitivity ; pregnancy; taking ocp or ovulation stimulation drugs; current use of drugs affecting sexual performance; Previous diagnosis of an organic cause for sexual dysfunction by an experienced physician; Taking vasodilator drugs and drugs that interact with metformin, sildenafil, and melatonin

Intervention groups

Intervention group A: sildenafil (daily 25 mg of sildenafil citrate (Vizarcin)) along with metformin tablets (500 mg orally three times a day); Intervention group B: melatonin (daily 3 mg melatonin tablets (Razak Pharmaceutical Company, Iran) along with metformin tablets (500 mg three times a day orally); intervention group C: melatonin (daily 3 mg melatonin tablets Razak Pharmaceutical Company , Iran) along with sildenafil (25 mg sildenafil citrate (Vizarcin) daily) along with metformin tablets (500 mg orally three times a day); control group: metformin tablets (500 mg orally three times a day)

Main outcome variables

Sexual function

General information

Reason for update

In the random assignment section, the names of the groups were written in two groups.

Acronym

IRCT registration information

IRCT registration number: **IRCT20160524028038N13**

Registration date: **2022-12-09, 1401/09/18**

Registration timing: **prospective**

Last update: **2022-12-12, 1401/09/21**

Update count: **1**

Registration date

2022-12-09, 1401/09/18

Registrant information

Name

Fatemeh Bazarganipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3366 6367

Email address

bazarganipour@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-21, 1401/09/30

Expected recruitment end date

2023-02-19, 1401/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of sildenafil along with melatonin on the sexual function of patients with polycystic ovary syndrome treated with metformin.

Public title

The effect of sildenafil and melatonin on sexual function

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged 18 to 45 years Body mass index 19-25 Confirmation of polycystic ovary syndrome based on the Rotterdam criteria

Exclusion criteria:

Patients who do not want to cooperate. Sildenafil sensitivity and intolerance to side effects (hot flashes, vision disorders, severe drop in blood pressure and hearing disorders) pregnancy Taking ocp or ovulation stimulation drugs Existence of severe mental conditions since 6 months before the research, which has an adverse effect on the patient's quality of life Suffering from a severe degree of depression and anxiety according to the depression and anxiety questionnaire based on the Beck depression and anxiety questionnaire Current use of psychiatric medications Language or cognitive problems preventing the patient from completing the questionnaire smoking Current use of drugs affecting sexual performance Previous diagnosis of an organic cause for sexual dysfunction by an experienced physician Taking vasodilator drugs and drugs that interact with metformin, sildenafil, and melatonin

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **216**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is simple. The random allocation sequence will be determined using the "computer Random generation" computer program. The sealed envelopes encoded and non-transparent (A, B, C, D) for the allocation of subjects to intervention (A, B, C) and control (D) groups will be used.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Yasuj University of Medical Sciences

Street address

No. 7916839319, Shahid Jalil Ave., Yasuj Town, kohgiluyeh and boyer-ahmad

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7916839319

Approval date

2022-10-12, 1401/07/20

Ethics committee reference number

IR.YUMS.REC.1401.116

Health conditions studied**1****Description of health condition studied**

polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes**1****Description**

Sexual function

Timepoint

Before the intervention and three after the intervention

Method of measurement

FSFI sexual function questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Sildenafil (sildenafil citrate (Vizarcin)

25 mg daily) + metformin tablets (500 mg three times a day orally)
Category
Treatment - Drugs

2

Description
Intervention group: melatonin (3 mg of melatonin tablets daily (Razak Pharmaceutical Company, Iran) along with metformin tablets (500 mg orally three times a day)
Category
Treatment - Drugs

3

Description
Intervention group: Melatonin (3 mg melatonin tablets per day, Razak Pharmaceutical Company, Iran) along with sildenafil (25 mg sildenafil citrate (Vizarsin) per day) along with metformin tablets (500 mg orally three times a day)
Category
Treatment - Drugs

4

Description
Control group: metformin tablets (500 mg orally three times a day)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Yasuj University of medical sciences, Shahid Mofateh Clinic
Full name of responsible person
Sadaf Abbasi
Street address
Yasuj University of medical sciences, Shahid Mofateh Clinic, Motahari Bulvard
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sadaf.abbasi1365@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Amin Hosseini
Street address
No. 7916839319, Shahid Jalil Ave., Yasuj Town, Kohgiluyeh and Boyer-Ahmad
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Phone
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Email
amin.hosseini@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Sadaf Abbasi
Position
student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
No. 7916839319, Shahid Jalil Ave., Yasuj Town, Kohgiluyeh and Boyer-Ahmad
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

student

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Person responsible for updating data

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Sadaf Abbasi

Position

student