Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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+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-Boyrahmad
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

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7916839319

Phone

+98 74 3333 7251

Email

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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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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Province

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Person responsible for scientific 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
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Person responsible for updating data

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
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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