Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Evaluation of the effect of sildenafil along with metformin 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 metformin 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 108 patients; phase 3; randomized using block randomization method

Settings and conduct
Eligible patients referred to infertitlity Clinic of Hormozgan 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.

Intervention groups
Intervention group : sildenafil (daily 25 mg of sildenafil citrate (Vizarcin)) 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

Acronym

IRCT registration information

IRCT registration number: **IRCT20160524028038N16**
Registration date: **2023-02-08, 1401/11/19**
Registration timing: **prospective**

Last update: **2023-02-08, 1401/11/19**
Update count: **0**

Registration date
2023-02-08, 1401/11/19

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
2023-02-19, 1401/11/30

Expected recruitment end date
2023-05-21, 1402/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

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

Public title
The effect of sildenafil and metformin 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, silde.
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: **108**
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) for the allocation of subjects to intervention and control 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 Hormozgan University of Medical Sciences
Street address
Vice chancellor of research, Shahid Mohamadi Hospital, Bandarabbas, Hormozgan
City
Bandarabbas
Province
Hormozgan
Postal code
7916839319
Approval date
2023-01-14, 1401/10/24
Ethics committee reference number
IR.HUMS.REC.1401.336

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
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
Control group: metformin tablets (500 mg orally three times a day)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility center affiliated to Hormozgan University of Medical Sciences
Full name of responsible person
Maryam Azizi
Street address
Parastar Street, Bandarabbas, Hormozgan
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Bandarabbas,
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Postal code
7919915519
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Email
Maryamazizikut86@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
دانشگاه علوم پزشکی بندرعباس نام کاملMedical Sciences فرد مسوول Teymoor Aghamolaei
Street address
Shahid Mohamadi Hospital, Bandarabbas, Hormozgan
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taghamolaei@hums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bandare-abbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Maryam Azizi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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Full name of responsible person

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Position

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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

No - There is not 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