

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Evaluation of the effect of myoinositol on the sexual function of patients with polycystic ovary syndrome treated with cyproterone compound

Protocol summary

Study aim

Evaluation of the effect of myoinositol on the sexual function of patients with polycystic ovary syndrome treated with cyproterone compound

Design

clinical trial with a control group; with parallel groups; Randomized; Designed in 60 patients; phase 3; randomized using block randomization method

Settings and conduct

Eligible patients referred to Mofateh Clinic of Yasuj University of Medical Sciences will be divided into four groups of 30 people and sexual performance will be measured.

Participants/Inclusion and exclusion criteria

Eligibility conditions: age 18 to 40 years, Confirmation of polycystic ovary syndrome based on the Rotterdam criteria, Iranian, Absence of severe mental conditions since six months before the research, Not suffering from severe depression and anxiety according to the depression and anxiety questionnaire, No current use of psychiatric medications, No language or cognitive problems preventing the patient from completing the questionnaire, No smoking, No current use of drugs affecting sexual function, Failure to previously diagnose an organic cause for sexual dysfunction by an experienced physician, Currently taking cyproterone compound tablets as prescribed by the gynecologist

Intervention groups

Intervention group : inofolic powder (2 grams myoinositol + 400 micrograms folic acid; daily, 12 weeks) along with cyproterone compound tablet (21 days per monthly cycle, 3 months); control group: Cyproterone compound tablet (21 days per monthly cycle, 3 months)

Main outcome variables

Sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160524028038N17**

Registration date: **2023-07-03, 1402/04/12**

Registration timing: **prospective**

Last update: **2023-07-03, 1402/04/12**

Update count: **0**

Registration date

2023-07-03, 1402/04/12

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

2023-07-08, 1402/04/17

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of myoinositol on the sexual function of patients with polycystic ovary syndrome treated with cyproterone compound

Public title

myoinositol and sexual function

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

age 18 to 40 years Confirmation of polycystic ovary syndrome based on the Rotterdam criteria Iranian Absence of severe mental conditions since six months before the research Not suffering from severe depression and anxiety according to the depression and anxiety questionnaire No current use of psychiatric medications No language or cognitive problems preventing the patient from completing the questionnaire No smoking No current use of drugs affecting sexual function Failure to previously diagnose an organic cause for sexual dysfunction by an experienced physician Currently taking cyproterone compound tablets as prescribed by the gynecologist

Exclusion criteria:

Patients who do not want to cooperate. Pregnancy during study

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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 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

2023-06-14, 1402/03/24

Ethics committee reference number

IR.YUMS.REC.1402.050

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: inofolic powder (2 grams myoinositol + 400 micrograms folic acid; daily,12 weeks) along with cyproterone compound tablet (21 days per monthly cycle, 3 months)

Category

Treatment - Drugs

2**Description**

Control group: Cyproterone compound tablet (21 days per monthly cycle, 3 months)

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

Parvin-Alsadat Eslamnik

Street address

Yasuj University of medical sciences, Shahid Mofateh Clinic, Motahari Bulvar

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+98 912 425 8623

Email

f.bazarganipour@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

Parvin-Alsadat Eslamnik

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Parvin-Alsadat Eslamnik

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Person responsible for updating data

Contact

Name of organization / entity

Yasouj University of Medical Sciences

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