

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation of the effect of Lactofem probiotic supplement on sexual function in patients with different phenotypes of polycystic ovary syndrome undergoing cyproterone compound.

Protocol summary

Study aim

Evaluation of the effect of Lactofem probiotic supplement on sexual function in patients with different phenotypes of polycystic ovary syndrome undergoing cyproterone compound

Design

clinical trial with 8 intervention and control groups; with parallel groups; Randomized; Designed in 480 patients, phase 3, randomization using block method

Settings and conduct

Eligible patients referred to Muftah Clinic of Yasuj University of Medical Sciences will be divided into eight groups of 60 people according to phenotype and sexual function 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 groups (phenotype A, B, C, D): cyproterone compound tablets (21 days in each monthly cycle, for 3 months) along with Lactofem capsules (500 mg, manufactured by Bio Fermentation Company, Iran) orally, daily, for 3 months) Control groups (phenotype A, B, C, D): cyproterone compound tablets (21 days per monthly cycle, for 3 months)

Main outcome variables

Sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160524028038N18**

Registration date: **2024-01-04, 1402/10/14**

Registration timing: **prospective**

Last update: **2024-01-04, 1402/10/14**

Update count: **0**

Registration date

2024-01-04, 1402/10/14

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

2024-02-09, 1402/11/20

Expected recruitment end date

2025-03-18, 1403/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Lactofem probiotic supplement on sexual function in patients with different phenotypes of polycystic ovary syndrome undergoing cyproterone compound.

Public title

Evaluation of the effect of Lactofem probiotic supplement on sexual function in patients with polycystic ovary syndrome

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 language or cognitive problems preventing the patient from completing the questionnaire No current use of drugs affecting sexual function No smoking Failure to previously diagnose an organic cause for sexual dysfunction by an experienced physician No current use of psychiatric medications 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: **480**

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,a,B,b,C,c,D,d) for the allocation of subjects to intervention (A, B, C, D)and control (a, b, c, 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

2023-12-20, 1402/09/29

Ethics committee reference number

IR.YUMS.REC.1402.149

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: (phenotype A): cyproterone compound tablets (21 days in each monthly cycle, for 3 months) along with Lactofem capsules (500 mg, manufactured by Zit-takhammir, Iran, orally, daily, for 3 months)

Category

Treatment - Drugs

2**Description**

Intervention group: (phenotype B): cyproterone compound tablets (21 days in each monthly cycle, for 3 months) along with Lactofem capsules (500 mg, manufactured by Zit-takhammir, Iran, orally, daily, for 3 months)

Category

Treatment - Drugs

3**Description**

Intervention group: (phenotype C): cyproterone compound tablets (21 days in each monthly cycle, for 3 months) along with Lactofem capsules (500 mg, manufactured by Zit-takhammir, Iran, orally, daily, for 3 months)

Category

Treatment - Drugs

4**Description**

Intervention group: (phenotype D): cyproterone compound tablets (21 days in each monthly cycle, for 3 months) along with Lactofem capsules (500 mg, manufactured by Zit-takhammir, Iran, orally, daily, for 3 months)

Category

Treatment - Drugs

5**Description**

Control group (phenotype A): cyproterone compound tablets (21 days per monthly cycle, for 3 months)

Category

Treatment - Drugs

6**Description**

Control group (phenotype B): cyproterone compound tablets (21 days per monthly cycle, for 3 months)

Category

Treatment - Drugs

7**Description**

Control group (phenotype C): cyproterone compound tablets (21 days per monthly cycle, for 3 months)

Category

Treatment - Drugs

8**Description**

Control group (phenotype D): cyproterone compound

tablets (21 days per monthly cycle, for 3 months)

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Yasuj University of Medical Sciences

Full name of responsible person

Zahra Asadi

Street address

No. 7916839319, Shahid Jalil Ave., Yasuj Town, Kohgiluyeh and Boyer-Ahmad

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7916839319

Phone

+98 917 793 1581

Email

zasadik66@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

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7916839319

Phone

+98 74 3333 7251

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
Zahra Asadi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
No. 7916839319, Shahid Jalil Ave., Yasuj Town,
Kohgiluyeh and Boyer-Ahmad
City
Yasuj
Province
Kohgiluyeh-va-Boyerahmad
Postal code
7916839319
Phone
+98 917 793 1581
Email
zasadik66@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Zahra Asadi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Yasuj University of medical sciences, Shahid Mofateh
Clinic, Motahari Bulvar
City
Yasuj

Province
Kohgiluyeh-va-Boyerahmad
Postal code
7916839319
Phone
+98 917 793 1581
Email
zasadik66@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Zahra Asadi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Yasuj University of medical sciences, Shahid Mofateh
Clinic, Motahari Bulvar
City
Yasuj
Province
Kohgiluyeh-va-Boyerahmad
Postal code
7916839319
Phone
+98 917 793 1581
Email
zasadik66@gmail.com

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