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-Boyrahmad

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-Boyrahmad
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-Boyrahmad
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
Kohgilouyeh-va-Boyrahmad
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 Bulvard
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
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 Bulvard
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
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