

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of oral probiotic on sexual function in patients with polycystic ovary syndrome treated with letrozole

Protocol summary

Study aim

Determination of the effect of oral probiotic on sexual function in women with polycystic ovary syndrome treated with letrozole

Design

This study is a randomized clinical trial study that will be performed on 40 patients with polycystic ovary syndrome in the infertility clinic of Hormozgan University of Medical Sciences in 2020.

Settings and conduct

In the intervention group, one Lactofem capsule (including Lactobacillus acidophilus 109 , 2, Bifidobacterium bifidus 109 , 2, Lactobacillus rutri 2 × 109, Lactobacillus fermentum 109 × 2; capsule weight of 500 mg bio-capsule) was administered daily for one month orally. In the second month, letrozole at a dose of 2.5 mg daily from the third day of the menstrual cycle for 5 days with daily use of lactofem capsules for one month. In the control group, letrozole alone will be administered 2.5 days from the third day of the menstrual cycle for 5 days in the second month. The sexual function questionnaire will be completed before and two months after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18-38 year, Definition of pcos based on the Rotterdam standard, Inability to conceive after one year of regular intercourse without the use of contraceptives, Absence of tubular factors, anatomical and male causes of infertility, Healthy uterine cavity, Normal levels of thyroid hormones. Exclusion criteria: Other endocrine disorders such as hyperprolactinemia, Unwillingness to participate in the study, Use metformin Lack of follow-up

Intervention groups

Lactofem capsule (500 mg capsule) orally for two months with letrozole administration compared with letrozole alone

Main outcome variables

Sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160524028038N8**

Registration date: **2020-10-04, 1399/07/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-04, 1399/07/13**

Update count: **0**

Registration date

2020-10-04, 1399/07/13

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

2020-09-20, 1399/06/30

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral probiotic on sexual function in patients with polycystic ovary syndrome treated with letrozole

Public title

oral probiotic and sexual function

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18-38 year
Definition of pcos based on the Rotterdam standard
Inability to conceive after one year of regular intercourse without the use of contraceptives
Absence of tubular factors, anatomical and male causes of infertility
Healthy uterine cavity
Normal levels of thyroid hormones

Exclusion criteria:

Other endocrine disorders such as hyperprolactinemia
Unwillingness to participate in the study
Use metformin
Lack of follow-up

Age

From **18 years** old to **38 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

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 and B) for the allocation of subjects to intervention (A) and control (B) 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

2020-09-15, 1399/06/25

Ethics committee reference number

IR.HUMS.REC.1399.326

Health conditions studied**1****Description of health condition studied**

polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes**1****Description**

Sexual function

Timepoint

Before the intervention and two months after the intervention

Method of measurement

FSFI sexual function questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: one Lactofem capsule (including Lactobacillus acidophilus 10⁹ × 2, Bifidobacterium bifidus 10⁹ × 2, Lactobacillus rutri 2 × 10⁹, Lactobacillus fermentum 10⁹ × 2; capsule weight of 500 mg bio-capsule) was administered daily for one month orally. In the second month, letrozole at a dose of 2.5 mg daily from the third day of the menstrual cycle for 5 days with daily use of lactofem capsules for one month.

Category

Treatment - Drugs

2**Description**

Control group: letrozole alone will be administered 2.5 days from the third day of the menstrual cycle for 5 days in the second month.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Bandare-abbas University of Medical Sciences

Full name of responsible person

Maryam Azizi

Street address

Shahid Mohamadi Hospital, Bandarabbas, Hormozgan

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maryamazikut86@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Teymoor Aghamolaei

Street address

Vice chancellor of research, Shahid Mohamadi Hospital, Bandarabbas, Hormozgan

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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

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Person responsible for updating data

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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