

# 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 10<sup>9</sup> × 2, Bifidobacterium bifidus 10<sup>9</sup> × 2, Lactobacillus rutri 2 × 10<sup>9</sup>, Lactobacillus fermentum 10<sup>9</sup> × 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 mg daily 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

**City**

Bandarabbas

**Province**

Hormozgan

**Postal code**

7916839319

**Phone**

+98 76 3366 6365

**Email**

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

**City**

Bandarabbas

**Province**

Hormozgan

**Postal code**

معاونت پژوهشی دانشگاه

**Phone**

+98 76 3333 7192

**Email**

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**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

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

**City**

Bandarabbas

**Province**

Hormozgan

**Postal code**

7916839319

**Phone**

076333666365

**Email**

maryamazikut86@gmail.com

## Person responsible for scientific 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

**Street address**

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

**City**

Bandarabbas

**Province**

Hormozgan

**Postal code**

7916839319

**Phone**

076333666365

**Email**

maryamazikut86@gmail.com

## Person responsible for updating data

#### 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

**Street address**

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

**City**

Bandarabbas

**Province**

Hormozgan

**Postal code**

7916839319

**Phone**

076333666365

**Email**

maryamazikut86@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