

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Fecal microbiota transplantation (FMT) for treatment of polycystic ovary syndrome: a clinical trial phase I

Protocol summary

Study aim

Removal of suspected microbiome in PCOS patients and replacement with intestinal microbiome of healthy person

Design

Clinical trial with self-control, no blindness, non-randomized

Settings and conduct

Background: Treatment of PCOS Place: Bushehr University of Medical Sciences Methods: Fifteen PCOS patients will be enrolled with the above mentioned criteria as the recipient group , and 15 individuals eligible as the recipient group will be introduced. Then, necessary tests will be carried out in both groups. The stool sample is taken from the group and analyzed. The provided capsules will be administered. The patients will be followed up for a period of 6 months.

Participants/Inclusion and exclusion criteria

Group entry criteria: PCOS patient's sister Women aged 15-59 years old Healthy person Fertile with regular menstrual cycle Should have normal BMI. Six months of antibiotics free. Group departure criteria: Any digestive disease Any chronic infectious disease Having high-risk social behaviors History of recent antibiotic consumption consumption of allergen foods

Intervention groups

Criteria for entering the recipient group: Women of reproductive age 15-35 menstrual irregularity hyperandrogenism Ultrasound with polycystic ovary symptoms Lack of other diseases Secondary amenorrhea for more than 3 months Non-smoker No addiction No liquor Obesity Departure criteria for the recipient group: History of any digestive disease Immune suppression Partial or complete recovery of PCOS after medications Allergy to various foods. Chronic infectious diarrhea Consumption of antibiotics 3 days before the transplant Any malignancy Inherited diseases Cushing's disease Acromegaly and gigantism Diabetes

Main outcome variables

Removing PCOS symptoms Removing irregular mensuration Removal of secondary amenorrhea Removing symptoms of hyperandrogenism Removing hyperandrogenemia Decreasing the relative obesity

General information

Reason for update

Acronym

پیوند میکروبیوم

IRCT registration information

IRCT registration number: **IRCT20190523043674N1**

Registration date: **2019-07-10, 1398/04/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-10, 1398/04/19**

Update count: **0**

Registration date

2019-07-10, 1398/04/19

Registrant information

Name

Katayoun Vahdat

Name of organization / entity

The Persian Gulf Biomedical Research Institute

Country

Iran (Islamic Republic of)

Phone

+98 77 3355 7755

Email address

k.vahdat@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Fecal microbiota transplantation (FMT) for treatment of polycystic ovary syndrome: a clinical trial phase I

Public title

Effect of fecal microbiota transplantation in treatment of PCOS

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Adult women 15-35 Currently diagnosed PCOS patient without treatment PCOS patient with long time treatment According to Rotterdam criteria patient must have menstrual irregularity, hyperandrogenism and PCOS ultrasonography indices and must not have other diseases (at least two criteria) More than 1 month menstrual irregularity More than 3 months secondary amenorrhea Hyperandrogenism signs including acne and hirsutism Hyperandrogenemia (total testosterone of serum >0/5 ng/mL) Non-smoker, without any addiction and non-alcohol consumer patients Obese patient (BMI>20) Abnormal uterine bleeding

Exclusion criteria:

Any GI disorders Immuno-compromised patients or usage of immuno-suppressant drugs Improving of PCO symptoms after treatment with drugs Food Allergy Chronic diarrhea Antibiotic intake 3 days before transplantation Any history of cancer Congenital diseases such as adrenal hyperplasia Cushing's disease Acromegaly & Gigantism Type 1& 2 Diabetes

Age

From **15 years** old to **35 years** old

Gender

Female

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

University/Regional Research Ethics Committee
Bushehr province university of medical sciences

Street address

Bushehr University of Medical Sciences, Moallem St,
Bushehr, Iran.

City

Busheher

Province

Boushehr

Postal code

7514633341

Approval date

2019-05-20, 1398/02/30

Ethics committee reference number

IR.BPUMS.REC.1398.042

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

Poly-cystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

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

Removal of irregular mensuration

Timepoint

At the beginning of the study (before the intervention) and 7, 28 and 84 days after fecal microbial transplantation

Method of measurement

Questioner

2**Description**

Removal of ultrasonography PCOS symptoms

Timepoint

At the beginning of the study (before the intervention) and 7, 28 and 84 days after fecal microbial transplantation

Method of measurement

ultrasonography

3

Description

Removal of secondary amenorrhea

Timepoint

At the beginning of the study (before the intervention) and 7, 28 and 84 days after fecal microbial transplantation

Method of measurement

Questioner

4

Description

Removing hyperandrogenemia

Timepoint

At the beginning of the study (before the intervention) and 7, 28 and 84 days after fecal microbial transplantation

Method of measurement

Questioner and blood sexual hormone concentration

5

Description

Decreasing the relative obesity

Timepoint

At the beginning of the study (before the intervention) and 7, 28 and 84 days after fecal microbial transplantation

Method of measurement

Body mass index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:oral administration of 40 fecal microbial capsules by each patient in a 3-hour period which is produce in a laboratory in Bushehr University of Medical Sciences.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shohadaye Khalije Fars Hospital

Full name of responsible person

Katayoun Vahdat

Street address

Taleghani street

City

Bushehr

Province

Bushehr

Postal code

7517933755

Phone

+98 77 3345 5375

Fax

+98 77 3334 1828

Email

k.vahdat@bpums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Bushehr University of Medical Sciences

Full name of responsible person

Azam Amini

Street address

Moallem St, Bushehr, Iran.

City

Bushehr

Province

Bushehr

Postal code

7514633341

Phone

+98 77 3332 2081

Fax

+98 77 3334 1828

Email

foreign.chancellor@bpums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Bushehr 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**

Bushehr University of Medical Sciences

Full name of responsible person

Katayoun Vahdat

Position

Professor of Infectious Diseases

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Persian Gulf Biomedical Research Institute, Boostan
19 Alley, Postal Code: 7514763448, Imam Khomeini
Street, Bushehr/I.R. Iran.

City

Boushehr

Province

Boushehr

Postal code

7514763448

Phone

+98 77 3334 1827

Email

k.vahdat@bpums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Katayoun Vahdat

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Iranian South Medical Journal Editorial Office, The
Persian Gulf Biomedical Research Institute, Boostan
19 Alley, Postal Code: 7514763448, Imam Khomeini
Street, Bushehr/I.R. Iran.

City

Boushehr

Province

Boushehr

Postal code

7514763448

Phone

+98 77 3334 1827

Email

k.vahdat@bpums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Katayoun Vahdat

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Iranian South Medical Journal Editorial Office, The
Persian Gulf Biomedical Research Institute, Boostan
19 Alley, Postal Code: 7514763448, Imam Khomeini
Street, Bushehr/I.R. Iran.

City

Boushehr

Province

Boushehr

Postal code

7514763448

Phone

+98 77 3334 1827

Email

k.vahdat@bpums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The whole potential data is publishable after being
unidentifiable

When the data will become available and for how long

Start to access the data: 6 months after publishing the
results

To whom data/document is available

Data will only be available to researchers working in
academic and scientific institutions

Under which criteria data/document could be used

Contact the e-mail of scientific responsible person for
project and obtain permission after providing data usage
goals

From where data/document is obtainable

Dr Katayun Vahdat: vahdatk@gmail.com Dr Amin
Tamadon: amintamaddon@yahoo.com

What processes are involved for a request to access data/document

1- Review the data request: 1 month 2- Data delivery: 1
week

Comments