

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The effect of synbiotic supplementation on placental uterine blood flow, lipid profile and glycemic index in pregnant women with polycystic ovary syndrome

Protocol summary

Study aim

The effect of synbiotic supplementation on placental uterine blood flow, lipid profile and glycemic index in pregnant women with polycystic ovary syndrome

Design

The present study is a clinical trial with a control group, with parallel groups, double-blind, randomized (using block randomization), phase 3 on 98 patients.

Settings and conduct

In this double-blind randomization clinical trial, pregnant women with polycystic ovaries will be divided into two equal intervention and placebo groups by means of block randomization. In the intervention group, the patients will take one Lactofem synbiotic supplement capsule daily from the 28th week of pregnancy to the end of the 37th week, and in the placebo group, they will receive the placebo capsule. Finally, the two groups are compared in terms of outcomes.

Participants/Inclusion and exclusion criteria

Conditions for inclusion in the study: pregnant mothers in the 28th and 37th weeks of pregnancy with polycystic ovaries referred to Arak Taleghani Hospital; age 18-50 years; Consent to participate in the study Conditions for not entering the study: history of congenital disease; History of pregnancy complications in previous pregnancies; Having a special diet or taking anti-inflammatory and sugar-lowering supplements in the last 6 months

Intervention groups

In the intervention group, patients will take one supplemental capsule of Synbiotic Lactofam from Zistakhmir company daily from the 28th week of pregnancy until the end of the 37th week, and in the placebo group, they will receive a placebo capsule with the same shape and dosage as the synbiotic group produced by Zistakhmir company.

Main outcome variables

Uterine and umbilical artery PI, birth weight, Apgar score at birth (first and fifth minutes), gestational age at delivery, preeclampsia, intrauterine growth restriction, fasting blood glucose, OGTT, lipid profile, HOMA index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191104045328N17**

Registration date: **2023-10-02, 1402/07/10**

Registration timing: **prospective**

Last update: **2023-10-02, 1402/07/10**

Update count: **0**

Registration date

2023-10-02, 1402/07/10

Registrant information

Name

Amin Haji seyed hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 86 3366 7583

Email address

amin.medstu@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-22, 1402/07/30

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of synbiotic supplementation on placental uterine blood flow, lipid profile and glycemic index in pregnant women with polycystic ovary syndrome

Public title
Effect of synbiotic supplement on placental uterine blood flow in patients with polycystic ovary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant mothers of 28 and 37 weeks of pregnancy with polycystic ovaries referred to Arak Taleghani Hospital. Age 18-50 years Consent to participate in the study
Exclusion criteria:
History of congenital disease History of chronic diseases such as diabetes, cancer, high blood pressure, liver or kidney failure, etc. History of intrauterine growth restriction or preeclampsia or pregnancy complications in previous pregnancies Having a special diet or taking anti-inflammatory and sugar-lowering supplements in the last 6 months

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **98**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants will be assigned to two intervention and control groups based on the randomization sequence that will be generated in advance. This sequence is unpredictable and its arrangement is completely random. Block randomization method with 8 blocks will be used to allocate the samples. In this way, using the site www.sealedenvelope.com, blocks of 8 letters A and B are randomly generated based on the sample size. The order of placement of letters A and B in each block from the first block to the last block is considered as a randomization sequence. The production of these blocks and their random sequence is completely done by this site and the researcher does not know how they are sequenced.

Blinding (investigator's opinion)
Double blinded

Blinding description
For this, one group will receive Lactofem capsules and

the other group will receive a starch capsule similar to Lactofem with the same duration and dosage. Therefore, the women participating in the study are not aware of the type of medicine. In addition, for blinding of the second type, the drugs are delivered by the supervisor in special envelopes to the obstetrics and gynecology assistant, and the supervisor gives them to the patients, and each patient They will be coded, so only the supervisor is aware of the type of medication and the relevant resident (the outcome assessor) is not aware of the patient's medication type.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2022-11-20, 1401/08/29

Ethics committee reference number

IR.ARAKMU.REC.1401.231

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

PI of the umbilical artery

Timepoint

in the 28th and 37th weeks of pregnancy

Method of measurement

Doppler ultrasound

2**Description**

Baby's birth weight

Timepoint

at birth

Method of measurement

scales

3**Description**

Apgar score

Timepoint

1st and 5th minute of birth

Method of measurement

Apgar chart

4**Description**

Gestational age at delivery

Timepoint

At the time of delivery

Method of measurement

time of birth

5**Description**

PI uterine artery

Timepoint

in the 28th and 37th weeks of pregnancy

Method of measurement

Doppler ultrasound

6**Description**

Preeclampsia

Timepoint

Monitoring during pregnancy

Method of measurement

Clinical trials and examinations

7**Description**

Intrauterine growth restriction

Timepoint

Monitoring during pregnancy

Method of measurement

sonography

8**Description**

fasting blood glucose

Timepoint

28th and 37th weeks of pregnancy

Method of measurement

Laboratory

9**Description**

Oral glucose tolerance tests

Timepoint

28th and 37th weeks of pregnancy

Method of measurement

Laboratory

10**Description**

Homeostatic Model Assessment for Insulin Resistance

Timepoint

28th and 37th weeks of pregnancy

Method of measurement

Laboratory

11**Description**

Lipid profile

Timepoint

28th and 37th weeks of pregnancy

Method of measurement

Laboratory

Secondary outcomes

empty

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

Intervention group: In the intervention group, patients will take one supplement capsule of Synbiotic Lactofem from Zisttakhmir company daily from the 28th week of pregnancy until the end of the 37th week.

Category

Treatment - Drugs

2**Description**

Control group: In the placebo group, they receive placebo capsules with the same shape and dosage as the synbiotic group, produced by Zisttakhmir.

Category

Placebo

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

Ayatollah Taleghani Hospital, Arak

Full name of responsible person

Dr. Khadijeh Nasri

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Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

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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

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Seidi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr. Nazila Eskandari

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.

When the data will become available and for how long

Access will be from 2024/01/20 to 2027/01/20 for 3 years.

To whom data/document is available

University researchers

Under which criteria data/document could be used

Academic researchers or university professors or students who intend to use the data of this study, after obtaining permission from the relevant people mentioned, can use the information of this study in the field of metallurgical studies or other relevant review studies. In addition, if requested, they can use the information of this study for the prerequisites of their future studies and the existence of questions and ambiguities. Using the information of this study is subject to mentioning the names and logos of the responsible persons in this study.

From where data/document is obtainable

Academic researchers and university professors can request the use of data from Dr. Nazila Eskandari after contacting the relevant professor by message or email. Dr. Nazila Eskandari: Phone: 09123417159 Email: nazilaeskandari1@gmail.com Address: Arak, Ayatollah Taleghani Hospital, Hospital Education Vice-Chancellor

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

Letter writing should be done with professors and universities.

Comments