

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of sodium-glucose co-transporter inhibitor on metabolic and hormonal profiles in polycystic ovary syndrome

Protocol summary

Study aim

Evaluate and compare impacts of dapagliflozin and metformin on hormonal and metabolic profiles of polycystic ovary syndrome (PCOS)

Design

An open-label, parallel group, not double blind, randomized trial on 100 women with PCOS. Randomization method: permutation block randomization method with blocks of four will be used. We assign different permutations to numbers 1 to 4 in the following order. 1.AABB 2.ABAB 3.ABBA 4.BBAA 5.BABA 6.BAAB

Settings and conduct

Women (100 participants) with PCOS will be randomized on a 1:1 ratio to receive either dapagliflozin 10 mg or Metformin 1500 mg daily. Participants will be attended three visits. During Visit 1, participants screen against inclusion and exclusion criteria by medical history and clinical examination, blood tests and anthropometric measurements. During Visit 2 (baseline) and Visit 3 (12-week follow-up), participants undergo anthropometric and blood tests.

Participants/Inclusion and exclusion criteria

Women aged 18-45 with PCOS with body mass more than 25 Cushing syndrome Inadequately controlled thyroid disease. Androgen-secreting tumor Pregnancy or intention to become pregnant Breast feeding Documented use of oral hormonal contraceptives and hormone-releasing implants, clomiphene citrate or estrogen modulators, gonadotropin-releasing hormone (GnRH) modulators Diagnosis of diabetes and use of antidiabetic agent Congenital adrenal hyperplasia due to 21-hydroxylase deficiency Hyperprolactinemia

Intervention groups

Treatment of women with PCOS aged 18-45 with a body mass index greater than or equal to 25, with dapagliflozin 10 mg or metformin 1500 mg daily for 3 months

Main outcome variables

Treat high fasting blood sugar and high blood pressure; reduction of plasma lipid and insulin level, androstenedione and total testosterone level; and reducing the body mass index and the waist to hip ratio

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240520061850N1**

Registration date: **2024-11-09, 1403/08/19**

Registration timing: **registered_while_recruiting**

Last update: **2024-11-09, 1403/08/19**

Update count: **0**

Registration date

2024-11-09, 1403/08/19

Registrant information

Name

Marjan Jeddi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3628 1569

Email address

jedim@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-21, 1403/04/01

Expected recruitment end date

2025-05-21, 1404/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of sodium-glucose co-transporter inhibitor on metabolic and hormonal profiles in polycystic ovary syndrome

Public title

Effect of metformin versus dapagliflozin in treatment of polycystic ovary syndrom.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women aged 18-45 with polycystic ovary syndrome with body mass index more than 25

Exclusion criteria:

Cushing syndrome inadequately controlled thyroid disease. androgen-secreting tumor pregnancy or intention to become pregnant Breast feeding documented use of oral hormonal contraceptives and hormone-releasing implants, clomiphene citrate or estrogen modulators, gonadotropin-releasing hormone (GnRH) modulators diagnosis of diabetes and use of antidiabetic agent congenital adrenal hyperplasia due to 21-hydroxylase deficiency hyperprolactinemia, age<18 year or >45 year,

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization Randomization method: The permutation block randomization method with blocks of four will be used. We assign different permutations to numbers 1 to 6 in the following order 1. AABB2. ABAB3. ABBA4. BBAA5. BABA6. BAAB Now, using the table of random numbers, we extract the numbers from the table and depending on whether one of the numbers 1 to 6 comes, select each of the blocks assigned to these numbers until 36 blocks of 4 are selected. If the numbers zero, 7, 8, and 9 come, we ignore them and continue this order to provide a complete list for the entire sample size.

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**

Ethnic Committee of Shiraz University of Medical Sciences

Street address

Office of Internal Medicine Department, Zand Blvd., Nemazee Hospital

City

Shiraz

Province

Fars

Postal code

713451414

Approval date

2024-05-20, 1403/02/31

Ethics committee reference number

IR.SUMS.MED.REC.1403.116

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

Polycystic ovary syndrome Based on Rotterdam Criteria

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

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

The percentage of people with fasting blood sugar \geq 100

Timepoint

Measuring fasting blood sugar at the beginning of the study and after 12 weeks of using metformin or dapagliflozin

Method of measurement

Fasting venous blood sampling

2**Description**

Blood pressure measurement

Timepoint

Measuring blood pressure at the beginning of the study and after 12 weeks of using metformin or dapagliflozin

Method of measurement

Sphygmomanometer

3

Description

Fasting plasma lipid level

Timepoint

Fasting plasma lipid measurement at the beginning of the study and after 12 weeks of using metformin or dapagliflozin

Method of measurement

Fasting venous blood sampling

4

Description

Fasting plasma insulin level

Timepoint

Fasting plasma insulin level measurement at the beginning of the study and after 12 weeks of using metformin or dapagliflozin

Method of measurement

Fasting venous blood sampling

5

Description

Fasting plasma androstenedione level

Timepoint

Fasting plasma androstenedione level measurement at the beginning of the study and after 12 weeks of using metformin or dapagliflozin

Method of measurement

Fasting venous blood sampling

6

Description

Total plasma testosterone

Timepoint

Fasting plasma testosterone level measurement at the beginning of the study and after 12 weeks of using metformin or dapagliflozin

Method of measurement

Fasting venous blood sampling

7

Description

C-reactive protein plasma level

Timepoint

Measuring the plasma level of C-reactive protein at the beginning of the study and after 12 weeks of using metformin or dapagliflozin

Method of measurement

Fasting venous blood sampling

8

Description

Measurement of waist/Hip ratio

Timepoint

Measuring waist/Hip ratio at the beginning of the study and after 12 weeks of using metformin or dapagliflozin

Method of measurement

Meter

9

Description

Body mass index

Timepoint

Measuring body mass index at the beginning of the study and after 12 weeks of using metformin or dapagliflozin

Method of measurement

Meter and scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group :Treatment of women with polycystic ovary syndrome aged 18-45 with a body mass index greater than or equal to 25, with metformin 500 mg TID for 3 months. Metformin is an oral hypoglycemic agent and belongs to the group of biguanides, which has been proven to play a role in the treatment of polycystic ovary syndrome. Educational sessions for patients of this group to explain the side effects and how to take the medicine are held at the first visit and then once a month. this drug is produced by Shafa Pharmaceutical Company.

Category

Treatment - Drugs

2

Description

Intervention group: Treatment of women with polycystic ovary syndrome aged 18-45 with a body mass index greater than or equal to 25, with dapagliflozin 10 md daily for 3 months. This blood sugar lowering drug is one of the drugs that inhibit the sodium-glucose transporter in the kidney, which lowers blood sugar by excreting glucose in the urine. Educational sessions for patients of this group to explain the side effects and how to take the medicine are held at the first visit and then once a month. This drug is produced by the Innovative Pharmaceutical Company of Kimia, under the name of Faxibet.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Nemazee Sq, Nemazee Hospital, Endocrinology and Metabolism Research Center

Full name of responsible person

Mrs. Maryam Kazemi

Street address

Nemazee Hospital, Zand Blvd., Nemazee Sq.,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Shilan Mozaffari
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Unit 4, No.8, Hamedan St, North kargar St, Tehran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Farnaz Kamali Haghghi Shirazi
Position
Non-academic Specialist
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Specialist
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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

There is no further 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