Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 ۱ to ۶ in the following order. ۱.AABB ۲.ABAB ۳.ABBA ۴.BBAA ۵.BABA ۶.BAAB

Settings and conduct
Women(۱۰۰ participants) with PCOS will be randomized on a ۱:۱ ratio to receive either dapagliflozin ۱۰ mg or Metformin ۱۵۰۰mg daily. Participants will be attended three visits. During Visit ۱, participants screen against inclusion and exclusion criteria by medical history and clinical examination ,blood tests and anthropometric measurements. During Visit ۲ (baseline) and Visit ۳ (۱۲-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-hydroxilase 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)

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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-hydroxilase defficiency 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 >/equal to 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
Sphygmomonometer

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.,
City

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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
Street address
Unit 4, No.8, Hamedan St, North kargar St, Tehran
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1418693911
Phone
+98 918 377 2141
Email
shilan.mozafari@gmail.com
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 Haghighi Shirazi
Position
Non-academic Specialist
Latest degree
Specialist
Other areas of specialty/work
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Latest degree
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