Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of the effect of metformin and empagliflozin on cardiometabolic, anthropometric and hormonal factors in women with polycystic ovarian syndrom

Protocol summary

Study aim

Comparing the effect of metformin and empagliflozin on cardiometabolic, anthropometric and hormonal factors of women with polycystic ovary syndrome.

Design

A clinical trial with a control group, with parallel groups, phase 3, randomized with random allocation software, is conducted on 50 patients.

Settings and conduct

This research is a clinical trial that is conducted on women aged 15 to 55 with polycystic ovary syndrome who refer to Imam Ali Shahrekord Clinic. For three months, the intervention group is treated with empagliflozin tablets and the control group is treated with metformin tablets. Before and after the intervention, anthropometric, hormonal and cardiometabolic factors are measured in both groups and compared at the end.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women aged 15-55, polycystic ovarian syndrome Exclusion criteria: Diabetes, pregnancy, urinary tract infection

Intervention groups

Patients are divided into 2 groups, empagliflozin group and metformin group. The intervention group received empagliflozin 10 mg tablets (Abidi company) daily for 3 months, and the control group received metformin 1000 mg tablets (Raha Daroo company) daily for three months.

Main outcome variables

Weight, body mass index, waist circumference, fasting sugar, Hba1c, total testosterone, 17-oh progesterone AST, ALT, HOMA-IR, CRP, triglyceride, LDL, HDL, total cholesterol, fasting insulin, Dehydroepiandrosterone

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220822055771N1**
Registration date: **2023-01-31, 1401/11/11**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-31, 1401/11/11**
Update count: **0**

Registration date

2023-01-31, 1401/11/11

Registrant information

Name

sara khosravi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3222 0016

Email address

st-khosravi.s@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of metformin and

empagliflozin on cardiometabolic, anthropometric and hormonal factors in women with polycystic ovarian syndrom

Public title
empagliflozin effect in polycystic ovarian syndrom
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
women between 15-55 years old polycystic ovarian syndrom
Exclusion criteria:
Glomerular filtration rate<30 pregnant liver disease diabet mellitus urinary tract infection chronic disease on hypertention treatment
Age
From **15 years** old to **55 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly divided into two groups using balanced block randomization with a sample size of 4 samples in each block and random allocation of samples in both groups with the help of random allocation software. The result of random allocation is done by the consultant of methodology and study statistics and the type of allocation treatment is recorded on paper and each sample is placed in a separate package with a sample order code. When surgery is performed, clinicians who do not know the outcome of the allocation process in each sample until the time of surgery will open the packages.
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
Research Ethics Committees of School of Medicine - Shahrekord University of Medical Sciences
Street address
School of Medicine, Rahmatieh
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Approval date
2022-06-22, 1401/04/01
Ethics committee reference number
IR.SKUMS.MED.REC.1401.024

Health conditions studied

1

Description of health condition studied
Polycystic ovarian syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Weight
Timepoint
before the start of the intervention and three months after the start of the intervention
Method of measurement
Digital scale

2

Description
body mass index
Timepoint
before the start of the intervention and three months after the start of the intervention
Method of measurement
Meter and scale

3

Description
waist circumfernce
Timepoint
before the start of the intervention and three months after the start of the intervention
Method of measurement
Measuring tape

4

Description
fasting blood sugar
Timepoint
before the start of the intervention and three months

after the start of the intervention
Method of measurement
spectrophotometry

5

Description
hba1c
Timepoint
before the start of the intervention and three months after the start of the intervention
Method of measurement
HPLC

6

Description
total testestrone
Timepoint
before the start of the intervention and three months after the start of the intervention
Method of measurement
ECLIA

7

Description
17-oh progesterone
Timepoint
before the start of the intervention and three months after the start of the intervention
Method of measurement
ELISA

8

Description
Dehydroepiandrosterone
Timepoint
before the start of the intervention and three months after the start of the intervention
Method of measurement
ELISA

9

Description
AST (aspartate aminotransferase)
Timepoint
before the start of the intervention and three months after the start of the intervention
Method of measurement
ELISA

10

Description
alanine transaminase(ALT)
Timepoint
before the start of the intervention and three months after the start of the intervention
Method of measurement
ELISA

11

Description
C-reactive protein (CRP)
Timepoint
before the start of the intervention and three months after the start of the intervention
Method of measurement
ELISA

12

Description
Triglycerides
Timepoint
before the start of the intervention and three months after the start of the intervention
Method of measurement
spectrophotometry

13

Description
LDL (low-density lipoprotein)
Timepoint
before the start of the intervention and three months after the start of the intervention
Method of measurement
spectrophotometry

14

Description
HDL (high-density lipoprotein)
Timepoint
before the start of the intervention and three months after the start of the intervention
Method of measurement
spectrophotometry

15

Description
total cholestrol
Timepoint
before the start of the intervention and three months after the start of the intervention
Method of measurement
spectrophotometry

16

Description
fasting insulin
Timepoint
before the start of the intervention and three months after the start of the intervention
Method of measurement
ELISA

17

Description
Insulin resistance

Timepoint
before the start of the intervention and three months after the start of the intervention
Method of measurement
HOMA.IR

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The people of this group are given empagliflozin 10 mg tablets (ABIDI company) once a day for three months.
Category
Treatment - Drugs

2

Description
Control group: The people of this group were given 1000 mg metformin tablets (Rahadaroo company) once a day for three months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Clinic of Shahrekord
Full name of responsible person
Sara Khosravi
Street address
Imam Ali Subspecialty Clinic, Shariati Boulevard, Shahrekord, Chaharmahal Va Bakhtiari
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Chahar-Mahal-va-Bakhtiari
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8816788640
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Email
St-khosravi.s@skums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Elham Reisi
Street address
Shahrekord Univrsity of Medical Sciencs, Kashani st.
City
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8815713471
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Vcrt@skums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Sara Khosravi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
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Hajar hospital, Parastar st.
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Person responsible for scientific inquiries

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Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Sara Khosravi

Position

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Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Postal code

8816754633

Phone

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available