

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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 circumference

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 testosterone

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 cholesterol

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,
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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 Sciences, Kashani st.

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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

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

Street address

Hajar hospital, Parastar st.

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Sara Khosravi

Position

Resident

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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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Other areas of specialty/work

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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