Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

A comparative analysis of effects of empagliflozin whit metformin on cardiometabolic factors and blood glucose of prediabetic patients

Protocol summary

Study aim
Comparison of average blood sugar indices (fasting blood sugar, fasting insulin, HbA1C, HOMA-Ir) and cardiometabolic factors (uric acid, cholesterol, triglyceride, HDL, LDL, CRP) of patients with prediabetes in three groups of metformin users 500 mg and empagliflozin 25 mg and empagliflozin 10 mg

Design
The clinical trial has three intervention groups, with parallel groups, double-blind, randomized with random allocation software, on 90 patients.

Settings and conduct
Imam Ali Shahrekord clinic

Participants/Inclusion and exclusion criteria
Inclusion criteria: pre-diabetic people aged 17-65 years whose pre-diabetes status has been newly diagnosed or has not yet been treated. Exclusion criteria: known cases of diabetes, history of urinary tract infection

Intervention groups
The study group includes hyperdiabetics (IFG and IGT) who were randomly divided into three intervention groups A, B, and C, and one intervention group received 500 mg of metforin, the other group received empagliflozin 25 mg, and the other group received empagliflozin. 10 mg is allocated

Main outcome variables
FBS; LDL; HDL CRP; TG; Cholesterol; Uric acid; Serum Fasting Insulin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220902055858N1**
Registration date: **2022-09-24, 1401/07/02**
Registration timing: **registered_while_recruiting**
Last update: **2022-09-24, 1401/07/02**
Update count: **0**

Registration date
2022-09-24, 1401/07/02

Registrant information
Name
Amin Moosavi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 38 3365 8225
Email address
amin.moosavi@skums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2022-12-22, 1401/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative analysis of effects of empagliflozin whit metformin on cardiometabolic factors and blood glucose of prediabetic patients

Public title
Effect of Empagliflozin in Prediabetes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:

Prediabetic Patient Age 17 to 65 years Not receiving blood sugar-lowering drugs

Exclusion criteria:

Known case of Diabetes A history of urinary tract infection

Age

From **17 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomized using random allocation software. In the software, the number of groups and the number of samples and the type of groups are determined. Then the numbers 1 to 90 are randomly assigned to three intervention groups. Group A, B and C; All three groups are subject to intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will be divided into three intervention groups (A, B, C) using random allocation software. Then envelopes are prepared according to the number of people participating in the study and numbers 1 to 90 are written on the envelopes and placed in each envelope using A, B and C software. In this way, when each person enters, a special envelope is opened for that person and according to the option inside the envelope, the person is assigned to one of the three intervention groups. The patients are not aware of the group to which they belong until the end of the study. The intervention will be done by someone other than the researcher.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Hajar Hospital, Parastar Ave., Kashani Blvd., Shahrekord

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816754633

Approval date

2022-06-22, 1401/04/01

Ethics committee reference number

IR.SKUMS.MED.REC.1401.025

Health conditions studied

1

Description of health condition studied

Impaired fasting glucose

ICD-10 code

R73.01

ICD-10 code description

Impaired fasting glucose

2

Description of health condition studied

Impaired glucose tolerance

ICD-10 code

R73.02

ICD-10 code description

Impaired glucose tolerance (oral)

Primary outcomes

1

Description

Fasting blood sugar

Timepoint

Measurement of fasting blood sugar at the beginning of the study and 12 weeks after the start of the intervention

Method of measurement

Peripheral blood biochemistry sample

2

Description

Postprandial blood sugar

Timepoint

Measurement of Postprandial blood sugar at the beginning of the study and 12 weeks after the start of the intervention

Method of measurement

Peripheral blood biochemistry sample

3

Description

Glycosylated hemoglobin

Timepoint

Measurement of Glycosylated hemoglobin at the beginning of the study and 12 weeks after the start of

the intervention

Method of measurement

Peripheral blood biochemistry sample

4

Description

Uric Acid level

Timepoint

Measurement of Uric Acid at the beginning of the study and 12 weeks after the start of the intervention

Method of measurement

Peripheral blood biochemistry sample

5

Description

C-Reactive Protein (CRP)

Timepoint

Measurement of CRP at the beginning of the study and 12 weeks after the start of the intervention

Method of measurement

Peripheral blood biochemistry sample

6

Description

cholesterol

Timepoint

Measurement of cholesterol at the beginning of the study and 12 weeks after the start of the intervention

Method of measurement

Peripheral blood biochemistry sample

7

Description

Low Density Lipoprotein (LDL)

Timepoint

Measurement of LDL at the beginning of the study and 12 weeks after the start of the intervention

Method of measurement

Peripheral blood biochemistry sample

8

Description

High Density Lipoprotein (HDL)

Timepoint

Measurement of HDL at the beginning of the study and 12 weeks after the start of the intervention

Method of measurement

Peripheral blood biochemistry sample

9

Description

Fasting Insulin Level

Timepoint

Measurement of Fasting Insulin Level at the beginning of the study and 12 weeks after the start of the intervention

Method of measurement

Peripheral blood biochemistry sample

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Prediabetic patients receiving metformin 500 mg twice a day ABIDI.Co for 3 months

Category

Treatment - Drugs

2

Description

Intervention group: Prediabetic patients receiving empagliflozin 10 mg once a day ABIDI.Co for 3 months

Category

Treatment - Drugs

3

Description

Intervention group: Prediabetic patients receiving empagliflozin 25 mg once a day ABIDI.Co for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Subspecialty clinic

Full name of responsible person

Amin Moosavi

Street address

Shariati Ave., Shahrekord

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+98 38 3224 2696

Email

info@skums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Mehraban Sadeghi

Street address

Kashani Blvd., Headquarters of Shahrekord University of Medical Science

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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
Amin Moosavi

Position
Resident of medical science

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

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Position
Resident of medical science

Latest degree
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Person responsible for updating data

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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

Information about the main outcome can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

Dr. Golshan Taghipur

Under which criteria data/document could be used

After printing the data results can be used.

From where data/document is obtainable

Data can be used by referring to e-mail.

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

The access period starts 6 months after the results are published.

Comments