

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison of the effect of Metformin and Empagliflozin in treatment of prediabetic patients.

Protocol summary

Study aim

Comparison of the effect of Metformin and Empagliflozin in treatment of prediabetic patients

Design

Clinical trial, Parallel group, Randomised trial, Single blind, in 100 patients

Settings and conduct

Study will start in Shahid Beheshti Hospital in Kashan. After the inclusion and exclusion criteria, the patients were randomly divided into two groups of 50 people, one group being treated with metformin 1000 mg daily and the other group being treated with Empagliflozin tablets 10 mg daily. Before the intervention, the patient's information is entered in the form of a questionnaire and after three months of taking the drug, all these factors are measured again in the referral and the results obtained with the data related to that person in three months. It is previously compared and the effectiveness of the drug is estimated. Finally, the data are compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Prediabetic patient Age between 30-80 years old BMI>25 Exclusion criteria: Treatment with hormones or drugs that interference glucose metabolism GFR< 45 Neurogenic bladder disorder Pregnant or breast feeding mothers Allergy to Empagliflozin or Metformin

Intervention groups

Empagliflozin tablet 10 mg daily

Main outcome variables

Blood pressure; Blood glucose; Blood lipid; Body mass index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210926052602N1**

Registration date: **2021-11-11, 1400/08/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-11, 1400/08/20**

Update count: **0**

Registration date

2021-11-11, 1400/08/20

Registrant information

Name

Sara Hasibi Taheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2284 5293

Email address

s.hasibi68@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-22, 1400/07/30

Expected recruitment end date

2022-04-20, 1401/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Metformin and Empagliflozin in treatment of prediabetic patients.

Public title

Comparison of the effect of Metformin and Empagliflozin in treatment of prediabetic patients.

Purpose

Screening

Inclusion/Exclusion criteria

Inclusion criteria:

Prediabetic patient Age between 30-80 years old BMI>25
Exclusion criteria:
Treatment with hormones or drugs that interference
glucose metabolism GFR< 45 Neurogenic bladder
disorder Pregnant or breast feeding mothers Allergy to
Empagliflozin or Metformin

Age
From **30 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomly divided (using the quadruple
block method and through the website
<https://www.sealedenvelope.com/> to prepare a
randomization list) into two groups of 50 people and a
group treated with metformin 1000 mg daily and the
other group are treated with empagliflozin 10 mg daily.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is a single-blind study in which participants
are unaware of the type of medication they receive. In
order to perform blinding, the manufacturer was asked to
prepare metformin and empagliflozin in exactly the same
way (same color, same size, same packaging). The lead
researcher and the physician are aware of the type of
medication the patient is taking, but the person
responsible for evaluating the statistical data will be
unaware of this.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical
Sciences

Street address

Shahid Beheshti Hospital, Ghotbe Ravandi Blvd,
Kashan.

City
Kashan
Province
Isfahan
Postal code
87159/81151
Approval date
2021-08-13, 1400/05/22
Ethics committee reference number
IR.KAUMS.REC.1400.032

Health conditions studied

1

Description of health condition studied

Prediabetes

ICD-10 code

R73.0

ICD-10 code description

Abnormal glucose tolerance test

Primary outcomes

1

Description

Blood glucose

Timepoint

3 months

Method of measurement

Blood sample

2

Description

Blood pressure

Timepoint

3 months

Method of measurement

Blood pressure monitor

3

Description

Weight

Timepoint

3 months

Method of measurement

Weight scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In this group, which includes 50
participants, empagliflozin tablets made by Actoverco

Pharmaceutical Company are given 10 mg in a daily dose for three months.

Category

Treatment - Drugs

2

Description

Intervention group 2: In this group, which includes 50 participants, metformin tablets made by Abidi Pharmaceutical Company are given 1000 mg in a daily dose for three months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital

Full name of responsible person

Sara Hasibi Taheri

Street address

Shahid Beheshti hospital, Ghotb ravandi Blvd, Kashan

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Tehran

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87159/81151

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+98 31 5554 0026

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s.hasibi68@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Kamal Esalatmanesh

Street address

Shahid Beheshti hospital, Ghotb ravandi Blvd, Kashan.

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kamalesalatmanesh@kaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Sara Hasibi Taheri

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Sara Hasibi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Medical doctor
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Internal Medicine
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Province
Isfahan

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

No idea

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

Undecided - It is not yet known if there will be 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