

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparing the effectiveness of Empagliflozin with Metformin in controlling Diabetes Mellitus in patients with post-organ transplant diabetes

Protocol summary

Study aim

Comparing the effectiveness of empagliflozin with metformin in reducing blood sugar in patients with diabetes after organ transplantation

Design

This study is a parallel, double-blind, randomized clinical trial in phase 3 on 40 patients; To compare the effectiveness of empagliflozin and metformin in reducing blood sugar in patients with diabetes after transplantation. For randomization, we will use the block randomization method.

Settings and conduct

Endocrine Clinic, Dr. Masih Deneshvari Hospital, Iran, Tehran. The study is double-blind. The main researcher and the patient are not aware of the type of drug. Only the pharmacist who delivers the medicine knows the type of medicine. The pharmacist delivers both types of medicine to the patient in capsules with the same appearance

Participants/Inclusion and exclusion criteria

Inclusion Criteria : At least 6 months have passed since patients transplant. No previous history of Diabetes mellitus or use of any blood sugar lowering medication. Diabetes diagnosis is done according to American Diabetes Association $6.5\% < \text{HbA1c} < 8\%$ Exclusion Criteria : Rejection or organ failure of the transplanted organ Pregnancy Any contraindications of Metformin Any contraindications of Empagliflozin BMI above 40 Severe liver failure Renal failure

Intervention groups

Group A participants receive empagliflozin 10 mg tablets (Iran, Tehran, Abidi Pharmaceutical Company) for 3 months. Group B participants receive Metformin 500 mg tablets (Iran, Alborz, Actoverco Pharmaceutical Company) for 3 months.

Main outcome variables

HbA1c, FBS, BS 2hPP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230315057726N1**

Registration date: **2023-08-26, 1402/06/04**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-26, 1402/06/04**

Update count: **0**

Registration date

2023-08-26, 1402/06/04

Registrant information

Name

Maryam Vasheghani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-01, 1402/05/10

Expected recruitment end date

2024-07-31, 1403/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of Empagliflozin with Metformin in controlling Diabetes Mellitus in patients with post-organ transplant diabetes

Public title

Comparing the effectiveness of Empagliflozin with Metformin in controlling Diabetes Mellitus in patients with post-organ transplant diabetes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

At least 6 months have passed since the patient's transplant No previous history of diabetes and use of any blood sugar-lowering medication Diagnosing diabetes according to the criteria of the American Diabetes Association $HbA1c < 8\%$ $HbA1c > 6.5\%$

Exclusion criteria:

Rejection of the transplanted organ in the patient Transplanted organ failure Pregnancy Age less than 18 years Any contraindication related to empagliflozin (allergy to the drug or its components, dialysis, diabetic ketoacidosis, hospitalization) The patient's unwillingness to participate in the study BMI above 40 Severe liver failure (enzymes more than 3 times the normal limit) or renal failure (creatinine more than 2), creatinine clearance below 60 Any contraindication related to Metformin (allergy to the drug or its components, dialysis, diabetic ketoacidosis, hospitalization)

Age

From 18 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization Individual Sealed envelopes As the numbers of each envelope are finished, the next envelope will be opened until the sample is completed. The principal investigator and the patient are unaware of the contents of the envelopes. Only the pharmacist who delivers the medicine; knows the type of medicine. The pharmacist delivers both types of medicine to the patient in capsules with the same appearance.

Blinding (investigator's opinion)

Double blinded

Blinding description

We will use block randomization to allocate the samples to intervention and control groups. For this purpose, we prepare four sheets of paper. On two sheets, we write the letter a for the treatment group of empagliflozin. Then on the other two sheets, we write the letter b for the treatment group of metformin. We mix the sheets

together and put 4 sheets (two sheets with the letter A and two sheets with the letter B) in the sealed envelope. With the referral of each qualified patient, one of the sheets will be randomly drawn, and based on this drawn sheet, whether it is a or b, they will be assigned to one of the above-mentioned two groups. It should be noted that we will not refer to the next envelope until all four sheets have been pulled out. After randomly pulling out all four sheets, we go to the next sealed envelope and repeat the above procedure for the next four patients until we reach the desired sample size. The main researcher and the patient are unaware of the contents of the envelopes. Only the pharmacist who delivers the medicine knows the type of medicine. The pharmacist delivers both types of medicine to the patient in capsules with the same appearance.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Islamic Azad Tehran Medical Sciences University - Pharmacy and Pharmac

Street address

School of Pharmacy and Pharmaceutical Sciences - Islamic Azad University of Medical Sciences, Tehran (Research Ethics Committee), yakhchal, Qolhak, Shariati

City

Tehran

Province

Tehran

Postal code

1941933111

Approval date

2023-01-02, 1401/10/12

Ethics committee reference number

IR.IAU.PS.REC.1401.374

Health conditions studied**1****Description of health condition studied**

Post Transplant Diabetes Mellitus

ICD-10 code

E13

ICD-10 code description

Other specified diabetes mellitus

Primary outcomes

1

Description

HbA1c

Timepoint

To compare the effectiveness of two drugs, empagliflozin and metformin, HbA1C of patients with Post Transplant Diabetes Mellitus(PTDM) is measured at the beginning of the study and 90 days after taking the drug.

Method of measurement

Blood Sample

Secondary outcomes

1

Description

FBS (fasting blood sugar)

Timepoint

To compare the effectiveness of two drugs, empagliflozin and metformin, FBS of patients with Post Transplant Diabetes Mellitus(PTDM) is measured at the beginning of the study and 90 days after taking the drug.

Method of measurement

Blood Sample

Intervention groups

1

Description

Intervention group A: Empagliflozin 10mg(Iran, Tehran, Abidi Pharmaceutical Company) for 3 months.

Category

Treatment - Drugs

2

Description

Intervention groupB: Metformin 500 mg(Iran, Alborz, Actoverco Pharmaceutical Company) for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih daneshavari hosrpital

Full name of responsible person

Maryam Vasheghani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mehdi Rajabi

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Yakhchal St., Qolhak, Dr.Shariati Blvd.

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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

Islamic Azad University

Proportion provided by this source

1

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

Islamic Azad University

Full name of responsible person

Amirhossein niknejad

Position

student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for scientific inquiries

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Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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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

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

Title and more details about the data/document

All project implementers have access to the data

When the data will become available and for how long

whole study time

To whom data/document is available

All project implementers

Under which criteria data/document could be used

The data is published together and without mentioning the name

From where data/document is obtainable

The chief investigator Dr. Maryam Vasheghani
mvasheghani9@sbmu.ac.ir Amirhossein Niknejad
amirhosseinniknejad@gmail.com

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

The applicants must send their request via E-Mail to the aforementioned researchers, and after the review and approval of the ethics committee of Islamic Azad University of Medical Sciences, the information will be provided to the applicant to the extent necessary without mentioning the names of patients.

Comments

The data is published together and without mentioning the name