

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 21 2712 2020

##### Email address

mvasheghani9@gmail.com

##### 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

#### Street address

Darbad , Niyavaran

#### City

Tehran

#### Province

Tehran

### Postal code

1956944413

### Phone

+98 21 2712 2020

### Email

mvasheghani9@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Islamic Azad University

#### Full name of responsible person

Mehdi Rajabi

#### Street address

Yakhchal St., Qolhak, Dr.Shariati Blvd.

#### City

Tehran

#### Province

Tehran

#### Postal code

1941933111

#### Phone

+98 21 2264 0052

#### Email

Int.affairs@tms.iau.ir

### 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

Medical Pharmacy

#### Street address

No. 6, Ravanpour St., Jordan Blvd., Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1966874513

**Phone**

+98 21 2202 3410

**Email**

amirhosseinniknejad@gmail.com

**Province**

Tehran

**Postal code**

1956944413

**Phone**

+98 21 2712 2020

**Email**

mvasheghani9@gmail.com

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Maryam Vasheghani

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Darabad, Niavaran

**City**

Tehran

**Province**

Tehran

**Postal code**

1956944413

**Phone**

+98 21 2712 2020

**Email**

mvasheghani9@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Maryam Vasheghani

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Darabad, Niavaran

**City**

Tehran

**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@sbm.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