

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Assessment of Empagliflozin effect on renal outcome in patients with type 2 diabetes mellitus

Protocol summary

Study aim

Determination the effect of the Empagliflozin on the course of diabetic nephropathy

Design

This study is double blind randomized clinical trial in which 96 eligible patients are randomly allocated to the treatment (receiving Empagliflozin 10 mg daily) and control (receiving placebo) groups.

Settings and conduct

Patients with type 2 diabetes referred to endocrinologist clinic in Imam Hosein hospital of Tehran. In this study, the therapist, patients, and the individual analyzing the results are blinded to the allocation of patients into two groups

Participants/Inclusion and exclusion criteria

Inclusion criteria : Age >18; type 2 diabetes ; GFR < 60 or albuminuria Exclusion criteria: Type 1 diabetes; heart attack and recent PCI; dialysis In recent 90s day ; GFR < 30; renal failure due to non diabetic causes; recurrent urinary infections ; history of diabetic foot amputation ; bladder cancer ; active diabetic foot infection; pregnancy and lactation ; major surgery in recent days.

Intervention groups

Case group: Empagliflozin 10mg daily recipient Control group: placebo recipient

Main outcome variables

Determination of Empagliflozin on glomerular filtration rate and albuminuria is considered as the primary outcome of this study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210906052395N1**

Registration date: **2022-03-16, 1400/12/25**

Registration timing: **retrospective**

Last update: **2022-03-16, 1400/12/25**

Update count: **0**

Registration date

2022-03-16, 1400/12/25

Registrant information

Name

Almas Khatami zenzian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4494 5438

Email address

almaskhatami@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-03-01, 1400/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of Empagliflozin effect on renal outcome in patients with type 2 diabetes mellitus

Public title

Effect of Empagliflozin in diabetic nephropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with type 2 diabetes over the age of 18 years

GFR<60 or albuminuria

Exclusion criteria:
Recent myocardial infarction and PCI Dialysis in the last ninety days GFR<30 Renal failure for reasons other than diabetes Recurrent urinary tract infections History of amputation due to diabetes Bladder cancer Active diabetic foot ulcer type 1 diabetes Pregnancy and lactation Major surgery performed in the last 28 days

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Number of 96 patients with diabetic nephropathy(GFR<60 or albuminuria>300)and inclusion criteria are selected then randomization is done by block method (Block stratified randomization). So that first all 4 blocks which include two codes A and B(drug and placebo) are prepared (4 non identical block arrangements and a total of 24 blocks) then random tables of random blocks are selected using placement. These blocks form a sample-sized sequence of codes A and B, each of which is randomly and confidentially and without considering the patients conditions ,is given to the doctor by the clinic secretary for prescription to the patient. The list of relevant codes will remain with the clinic secretary until the completion of the project. This method will provide both blinding and randomization.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participating patients were randomized by block method (block stratified randomization) and patients before entering the study would be informed and satisfied that in addition to the main treatment of glycemic control(metformin and /or insulin),accidentally and without their knowledge of the type of drug, will receive empagliflozin or placebo. Placebo and Empagliflozin would be designed identical and would be packed unanimously in identical boxes so patients in both groups will not be informed of their medication. One of the research team members would dedicate either placebo or Empagliflozin to patients(The first blinding step). Also, the researcher (physician) and the person who followed the patient's symptoms and conditions for months and records them, does not know the type of drug prescribed (A or B)(The second blinding step).

Placebo
Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Shahriari Square, Daneshjou Boulevard, Shahid Chamran Highwa

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2021-09-06, 1400/06/15

Ethics committee reference number

IR.SBMU.MSP.REC.1400.320

Health conditions studied

1

Description of health condition studied

Nephropathy and proteinuria in diabetic nephropathy patients taking empagliflozin

ICD-10 code

E08.21

ICD-10 code description

Diabetes mellitus due to underlying condition with diabetic nephropathy

Primary outcomes

1

Description

Body mass index(BMI)

Timepoint

Weeks 0-12-24-48

Method of measurement

Weight in kilograms divided by height squared in meters

2

Description

Evaluation of glycated hemoglobin or long-term blood sugar

Timepoint

Weeks 0-12-24-48

Method of measurement

Using the laboratory kit

3

Description

Fasting blood sugar measurement

Timepoint

Weeks 0-12-24-48

Method of measurement

Using the laboratory kit

4

Description

Measurement of glomerular filtration level for indirect evaluation of kidney status

Timepoint

Weeks 0-12-24-48

Method of measurement

Using the laboratory kit

5

Description

Measurement of urinary albumin / creatinine ratio

Timepoint

Weeks 0-12-24-48

Method of measurement

Using the laboratory kit

6

Description

Plasma creatinine measurement

Timepoint

Weeks 0-12-24-48

Method of measurement

Using the laboratory kit

7

Description

Measurement of urine albumin concentration

Timepoint

Weeks 0-12-24-48

Method of measurement

Using the laboratory kit

8

Description

Systolic and diastolic blood pressure

Timepoint

Weeks 0-12-24-48

Method of measurement

Barometer

9

Description

Duration of diabetes

Timepoint

Week 0

Method of measurement

Using questionnaire

10

Description

Evaluation of aspartate aminotransferase level for evaluation of liver function

Timepoint

Weeks 0-12-24-48

Method of measurement

Using the laboratory kit

11

Description

Evaluation of alanine aminotransferase level for evaluation of liver function

Timepoint

Weeks 0-12-24-48

Method of measurement

Using the laboratory kit

12

Description

Measurement of blood alkaline phosphatase level for evaluation of hepatic function

Timepoint

Weeks 0-12-24-48

Method of measurement

Using the laboratory kit

13

Description

Measurement of blood triglyceride levels

Timepoint

Weeks 0-12-24-48

Method of measurement

Using the laboratory kit

14

Description

Patient quality of life

Timepoint

Weeks 0-12-24-48

Method of measurement

Using questionnaire

15

Description

Measurement of blood cholesterol levels

Timepoint

Weeks 0-12-24-48

Method of measurement

Using the laboratory kit

16

Description

Measurement of blood LDL levels

Timepoint

Weeks 0-12-24-48

Method of measurement

Using the laboratory kit

17

Description

Measurement of blood HDL levels

Timepoint

Weeks 0-12-24-48

Method of measurement

Using the laboratory kit

18

Description

Insulin consumption

Timepoint

Weeks 0-12-24-48

Method of measurement

Using questionnaire

19

Description

Metformin consumption

Timepoint

Weeks 0-12-24-48

Method of measurement

Using questionnaire

20

Description

Angiotensin receptor blocker or Angiotensin converting enzyme inhibitors consumption

Timepoint

Weeks 0-12-24-48

Method of measurement

Using questionnaire

Secondary outcomes

1

Description

Lower limb edema

Timepoint

Weeks 0-12-24-48

Method of measurement

Questionnaire

2

Description

Complications and cardiac events

Timepoint

Weeks 0-12-24-48

Method of measurement

Questionnaire

3

Description

Incident of brain stroke

Timepoint

Weeks 0-12-24-48

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Receive 10 mg Empagliflozin tablets (Gloripa brand, Abidi Pharmaceutical Company,) one daily for 48 weeks in addition to the previous standard treatment(metformin and/or insulin)

Category

Treatment - Drugs

2

Description

Control group: Receive placebo tablets one daily for 48 weeks in addition to the previous standard treatment(metformin and/or insulin)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hosein hospital

Full name of responsible person

Almas khatami zenzian

Street address

Shahid Madani Ave,Imam Hosein hospital

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Almaskhatami@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahid Beheshti University of medical sciences
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Almas khatami zenzian
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
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Person responsible for scientific inquiries

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Shayesteh khalili
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Person responsible for updating data

Contact

Name of organization / entity
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Almas khatami zenzian
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Medical doctor
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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

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

At the end of the study and after the results are published, information about the study protocol, how to analyze the data, and the main outcomes are shared.

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

Researchers working in academia and in the drug industries

Under which criteria data/document could be used

Any analysis and use of the data and documentation submitted will be conditional with informing project executor and her consent.

From where data/document is obtainable

Refer to Dr.Almas khatami zenzian, principal Executor, for the documentation. Email: almaskhatami@gmail.com
Affiliations: Faculty of Medicine ,Shahid Beheshti University of Medical Sciences

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

The applicant should send an application to Dr.Almas khatami zenzian by email and she will respond as soon as possible after reviewing and consulting with other project members

Comments