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 patints into two groups
Participants/Inclusion and exclusion criteria
Inclusion criteria : Age >18;type 2 diabetes ;GFR<60 or albuminuria Exclusion criteria: Type1 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: Empagliflozin10mg 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 zenozian
Name of organization / entity
Country
Iran (Islamic Republic of)
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Email address
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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 type2 diabetes over the age of 18 years

GFR<60 or albuminuria

Exclusion criteria:

Recent myocatdial 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

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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 zenozian
Street address
Shahid Madani Ave,Imam Hosein hospital
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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 zenozian
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
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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
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 zenozian, 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 zenozian by email and she will respond as soon as possible after reviewing and consulting with other project members

Comments