Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of empagliflozin on renal events in non-diabetic chronic kidney disease patients with and without proteinuria. A double-blind placebo-controlled randomized clinical trial study

Protocol summary

Study aim

Determining the effects of empagliflozin independently of diabetes on proteinuria

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized through the website https://www.sealedenvelope.com/, with 229 patients participating in each group.

Settings and conduct

Through the website https://www.sealedenvelope.com/, the patients are randomly divided into drug and placebo groups and are examined for proteinuria at intervals of two months, four months and six months after the first visit, and all Drugs that have a proven role in reducing proteinuria are blocked in two groups so that their difference is not significant.The study will be carried out in the nephrology outpatient clinic located on the second floor of Imam Hossein Hospital clinics located on Shahid Madani street in patients with chronic kidney disease who do not have diabetes with personal consent under the direct supervision of nephorology specialist. Patients are evaluated at intervals of two, four and six months after the first visit

Participants/Inclusion and exclusion criteria

Patients over 18 years old Patients with 20≤eGFR≤75 mL/min/1.73m2 (calculated by MDRD formula) at the first visit Patients who meet the exclusion criteria will not be included in the study

Intervention groups

In the intervention group, 229 patients were treated with empagliflozin tablets at a dose of 10 mg daily, and in the control group, 229 patients were treated with placebo and were examined at intervals of two months, four months, and six months after the first visit.

Main outcome variables

The amount of reduction of microalbuminuria compared to the base level; Does a patient who had a normal urinalysis suffer from microalbuminuria or not? Checking the patient's GFR through the MDRD formula, which is specific to patients with chronic kidney failure, every two months and comparing it with the previous rate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211104052965N1**
Registration date: **2022-09-06, 1401/06/15**
Registration timing: **prospective**

Last update: **2022-09-06, 1401/06/15**
Update count: **0**

Registration date

2022-09-06, 1401/06/15

Registrant information

Name

Tahereh Sabaghian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2635 4167

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of empagliflozin on renal events in non-diabetic chronic kidney disease patients with and without proteinuria. A double-blind placebo-controlled randomized clinical trial study

Public title

Effect of empagliflozin on renal events in non-diabetic chronic kidney disease patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 18 years old Patients with 20≤eGFR≤75 mL/min/1.73m2 (calculated by MDRD formula) at the first visit

Exclusion criteria:

Dominant or autosomal recessive polycystic kidney disease, lupus nephritis or vasculitis with anti-neutrophil cytoplasmic antibody (ANCA) Received cytotoxic therapy, immunosuppressive therapy, or other immunologic therapy for primary or secondary renal disease within 6 months prior to the first visit Organ transplant history Blood pressure less than 90/60 mmHg Treatment with a sodium glucose cotransporter (SGLT 2) inhibitor within 8 weeks before the first visit or previous drug intolerance Frequent UTI Type 1 and 2 diabetes Class (NYHA) IV congestive heart failure at first visit Myocardial infarction, unstable angina, stroke and transient ischemic attack (TIA) within 12 weeks before the first visit Cardiovascular interventions such as CABG, PCI and valve replacement or repair within 12 weeks before the first visit Conditions such as malignancies where the patient does not have a good prognosis based on the clinical judgment of the researcher Active malignancy at the first visit Liver failure (AST and ALT more than three times normal and total bilirubin more than twice normal) Women prone to pregnancy who do not use contraceptive methods Pregnancy and breastfeeding Candida infection and low hygiene

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **458**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomized by simple individual randomization through https://www.sealedenvelope.com/simple-randomiser/v1/lists. Tablets are delivered to patients in sealed envelopes with drug and placebo codes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and health care provider who visit the patient and deliver the pills to the patient are completely blinded through the sealed and coded medicine envelope, and the person who packed the envelopes and designed the codes in Performance does not matter

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

Ethics Committee of Shahid Beheshti University of Medical Sciences, next to Ayatollah Taleghani Hospital, Shahid Aarabi street, Velenjak, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-07-24, 1401/05/02

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.284

Health conditions studied

1

Description of health condition studied

Chronic kidney disease

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

Primary outcomes

1

Description

The reduction of microalbuminuria

Timepoint
The second, fourth and sixth months after starting the study
Method of measurement
Laboratory measurement of albumin to creatinine ratio in random urine samples

2

Description
Does the patient experience an increase in the ratio of albumin to creatinine in the random urine sample or not?
Timepoint
The second, fourth and sixth months after starting the study
Method of measurement
Laboratory measurement of albumin to creatinine ratio in random urine samples

3

Description
Checking the patient's GFR through the MDRD formula every two months
Timepoint
The second, fourth and sixth months after starting the study
Method of measurement
Laboratory measurement of serum creatinine and calculation of GFR through the MDRD formula

Secondary outcomes

1

Description
The patient's condition in terms of high blood pressure and the use of antihypertensive drugs
Timepoint
The second, fourth and sixth months after starting the study
Method of measurement
Direct measurement of blood pressure

2

Description
Investigation of drug side effects such as urinary tract infection
Timepoint
The second, fourth and sixth months after starting the study
Method of measurement
Clinical interview

Intervention groups

1

Description
The intervention group, patients are treated with empagliflozin tablets manufactured by Alhavi Pharmaceutical Company with a dose of 10 mg daily in the morning after breakfast. The medicine is delivered to the patients in opaque bottles.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein hospital
Full name of responsible person
Tahereh Sabaghian
Street address
Imam Hossein hospital, Shahid Madani street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Tahereh Sabaghian
Position
assistant proffessor
Latest degree
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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All demographic, laboratory and clinical interview information and results will be provided anonymously
When the data will become available and for how long
After the article is published
To whom data/document is available
Information will be available to researchers of scientific institutions
Under which criteria data/document could be used
The data can be accessed by the authors in compliance with the copyright
From where data/document is obtainable
People can email hosseinamini96@yahoo.com and submit their request
What processes are involved for a request to access data/document
After stating the reason for the need for access, the data will be shared
Comments