

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 nephrology 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 $20 \leq \text{eGFR} \leq 75$ 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 $20 \leq \text{eGFR} \leq 75$ 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/lis>. 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

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Imam Hossein hospital, Shahid Madani street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shahin Salehi

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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

Specialist

Other areas of specialty/work

Internal Medicine

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

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Full name of responsible person

Tahereh Sabaghian

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Resident of clinical pharmacy

Latest degree

Subspecialist

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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