

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the renoprotective effects of SGLT2 inhibitor (Empagliflozin) in diabetic and non-diabetic kidney transplantation patients during a clinical trial at Imam Reza Educational and Medical Center in Kermanshah

Protocol summary

Study aim

Comparison of the renoprotective effects of SGLT2 inhibitor (Empagliflozin) in diabetic and non-diabetic kidney transplantation patients

Design

This study is a single-blinded clinical trial with a parallel design and a control group. The study population will include all patients with kidney transplantation referred to Imam Reza (AS) Hospital in Kermanshah. 28 eligible people will be selected conveniently. Random blocks are used for randomization and participants are assigned to two groups of intervention and control.

Settings and conduct

This study is a single-blinded clinical trial. In this study, participants will be unaware of the allocation of study groups and the dose of received medication. Participants do not know which group will receive the new drug or placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Urinary protein excretion less than ($<$) 500 mg to 3500 mg / g in a 24-hour urine set; Kidney transplant equal to or greater than 1 year ago; Stable state of renal function for at least the last three months; Sustained immunosuppressive therapy for at least the last 3 months
Exclusion criteria: Creatinine above 2; Patients who are pregnant or are breastfeeding; Patients with a history of type 1 diabetes; History of more than one kidney transplant; History of severe allergies or contraindications to empagliflozin; History of recurrent urinary tract infection

Intervention groups

The intervention group will receive empagliflozin at a dose of 10 mg daily with routine treatment (500 mg metformin two or three times daily). The control group will receive 10 mg of placebo daily (similar in appearance to empagliflozin) with routine treatment (500 mg of

metformin two or three times daily).

Main outcome variables

Serum creatinine, urinary protein content

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N168**

Registration date: **2021-05-10, 1400/02/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-10, 1400/02/20**

Update count: **0**

Registration date

2021-05-10, 1400/02/20

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-09, 1400/02/19

Expected recruitment end date

2021-08-10, 1400/05/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the renoprotective effects of SGLT2 inhibitor (Empagliflozin) in diabetic and non-diabetic kidney transplantation patients during a clinical trial at Imam Reza Educational and Medical Center in Kermanshah

Public title
Comparison of the renoprotective effects of SGLT2 inhibitor (Empagliflozin) in diabetic and non-diabetic kidney transplantation patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Urinary protein excretion less than (<) 500 mg to 3500 mg / g in a 24-hour urine set Kidney transplant equal to or greater than 1 year ago Stable state of renal function for at least the last three months Sustained immunosuppressive therapy for at least the last 3 months
Exclusion criteria:
Creatinine above 2 Patients who are pregnant or are breastfeeding Patients with a history of type 1 diabetes History of more than one kidney transplant; History of severe allergies or contraindications to empagliflozin History of recurrent urinary tract infection

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
• Participant

Sample size
Target sample size: **28**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the random number table, patients are divided into two groups . Each patient is assigned a 4-digit code based on the random number table, Based on the right number of patients code, the patients are divided into two groups. Patients whose last digit is 0, 2, 4, 6, 8 will be assigned to the intervention group and patients whose last digit is 1,3,5, 7, 9 will be assigned

Blinding (investigator's opinion)
Single blinded

Blinding description
In this single-blinded study, participants will be unaware of the allocation of study groups and the dose of received medication. Participants do not know which

group will receive the new drug or placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2021-03-08, 1399/12/18

Ethics committee reference number

ir.kums.rec.1399.1173

Health conditions studied

1

Description of health condition studied

kidney transplantation

ICD-10 code

T86.1

ICD-10 code description

Complications of kidney transplant

Primary outcomes

1

Description

Serum creatinine

Timepoint

The beginning of the study, the end of the 4th week, the end of the 8th week and the end of the 12th week

Method of measurement

Blood test

2

Description

Urine protein content

Timepoint

The beginning of the study, the end of the 4th week, the end of the 8th week and the end of the 12th week

Method of measurement
urine test

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group for 12 weeks will receive empagliflozin at a dose of 10 mg daily with routine treatment (500 mg metformin two or three times daily).

Category

Treatment - Drugs

2

Description

The control group for 12 weeks will receive 10 mg of placebo daily (similar in appearance to empagliflozin) with routine treatment (500 mg of metformin two or three times daily).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Seyed Mohammad Mostafavi

Street address

Emam Reza Hospital, Parastar Boulevard

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dr.mostafavi97@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Reza Khodarahmi

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Seyed Mohammad Mostafavi

Position

Resident of Urology

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Hossein Abdi

Position

Faculty member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Urology

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

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Position

Resident of Urology

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available