

# 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)

##### Phone

+98 83 1821 4653

##### Email address

fforoughi@kums.ac.ir

##### 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

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

##### Phone

+98 83 3427 6306

##### Email

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

##### Street address

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

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

##### Phone

+98 83 3836 0014

##### Email

rkhodarahmi@mbrc.ac.ir

#### 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

##### Street address

Emam Reza Hospital, Parastar Boulevard

##### City

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##### Province

Kermanshah

##### Postal code

6715847141

##### Phone

+98 83 3427 6306

##### Email

dr.mostafavi97@gmail.com

## 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

**Street address**

Emam Reza Hospital, Parastar Boulevard

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

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**Phone**

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**Email**

dr.mostafavi97@gmail.com

**Person responsible for updating data****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

**Street address**

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**Province**

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**Postal code**

6715847141

**Phone**

+98 83 3427 6306

**Email**

dr.mostafavi97@gmail.com

**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