

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation Renoprotective Effect SGLT2 inhibitors on Prognosis of Transplant Kidney Patients

Protocol summary

Study aim

Evaluation renoprotective effect of SGLT2 inhibitors on prognosis of kidney transplant.

Design

This is a randomized clinical trial with parallel control group; triple blind, phase 3 on 30 patients. For randomization, it was performed base on even or odd of national code.

Settings and conduct

The present study will be conducted as a triple blind clinical trial. The patient, the researcher and the analyst will not be aware of the treatment group of the patients. The research community includes patients with diabetic kidney transplant. The research sample includes patients with diabetic kidney transplant who refer to the medical education center Shariati, Tehran, Iran. 30 patients will be selected and included in the study based on the entry and exit criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age>18 y Stable renal function for three months- Consent of patient Sustained immunosuppressive therapy for three months- Transplantation > 1 y Diabetic patient according to criteria of American Diabetes Association Exclusion criteria: Surgery or medical conditions that affect of Absorption,Distribution- Metabolism or Excretion of drug- More than one transplant- Pregnancy or Breastfeeding- Allergy or Contraindications- Type 1 diabetes- Participation in any clinical study within 3 months before initial drug- GFR < 45- Frequent UTI- History of Alcohol use in12 months prior to initial drug- Donating blood or loss of 400 ml of blood 8 weeks before initial drug

Intervention groups

Intervention group: evaluation of drug effects on kidney function(GFR-Cr) and possible side effects. Control group: evaluation of effects of placebo.

Main outcome variables

Body mass index(BMI); blood pressure(BP); HbA1c; fasting blood sugar(FBS); glomerular filtration rate(GFR);

Hb; Hct; Uric acid; Na; K; creatinin

General information

Reason for update

Acronym

SGLT2 I

IRCT registration information

IRCT registration number: **IRCT20220708055414N1**

Registration date: **2023-02-19, 1401/11/30**

Registration timing: **retrospective**

Last update: **2023-02-19, 1401/11/30**

Update count: **0**

Registration date

2023-02-19, 1401/11/30

Registrant information

Name

fatemeh jalali khalil abadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 1000

Email address

fatemeh.jalali@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-22, 1401/05/31

Expected recruitment end date

2023-02-18, 1401/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation Renoprotective Effect SGLT2 inhibitors on Prognosis of Transplant Kidney Patients

Public title

Evaluation Renoprotective Effect SGLT2 inhibitors on Prognosis of Transplant Kidney Patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age>18 years old Stable state of renal function for at least the last three months Consent to participate in the study Sustained immunosuppressive therapy for at least three months Transplantation > one year ago Diabetic patient according to the criteria of the American Diabetes Association

Exclusion criteria:

Surgery or medical conditions that affect the rate of Absorption, Distribution and Metabolism or Excretion of the drug More than one transplant Pregnancy or Breastfeeding Allergy or Contraindications Type 1 diabetes Participation in any clinical study within 3 months before the initial dose GFR>45 Frequent UTI History of Alcohol use in the 12 months prior to the initial dose Donating blood or Removing 400 ml of blood is required 8 weeks before the initial dose

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly divided into two groups based on whether the last digit of the patient's national code is even or odd

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participant: People who were invited to participate in the study and after full explanations about the design and obtaining informed consent were divided into two intervention and control groups based on whether the national number was even or odd. Researcher: I, who aim to investigate the renoprotective effects of SGLT2 inhibitors on kidney transplant patients, and I am also responsible for collecting data and preparing the draft, without knowing whether the patient's medication box is a drug or a placebo based on the criteria for entering and

exiting the box. Medicines were provided to patients. Data analyst: one of the statisticians of the center who analyzes the data according to the numbers of the groups and does not know the control and intervention groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Faculty of Medicine, Tehran University of Medical Sciences

Street address

Faculty of Medicine, North Gate of University, Porsina St., Quds St., Elkhebal St.

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2021-07-02, 1400/04/11

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.423

Health conditions studied**1****Description of health condition studied**

Diabetes mellitus type 2

ICD-10 code

E11.2

ICD-10 code description

Type 2 diabetes mellitus with kidney complications

2**Description of health condition studied**

Transplant Kidney

ICD-10 code

Z94.0

ICD-10 code description

Kidney transplant status

Primary outcomes**1****Description**

Function of transplant kidney

Timepoint

At the beginning of the study-End of 8th 16th 24th week

Method of measurement

Glomerular filtration rate-Creatinine(lab test)

Secondary outcomes

1

Description

FBS

Timepoint

At the beginning of the study-End of 8th 16th 24th week

Method of measurement

Laboratory biochemical tests

2

Description

Hb A1C

Timepoint

At the beginning of the study-End of 8th 16th 24th week

Method of measurement

Laboratory biochemical tests

3

Description

Hemoglobin

Timepoint

At the beginning of the study-End of 8th 16th 24th week

Method of measurement

Laboratory biochemical tests

4

Description

Hematocrite

Timepoint

At the beginning of the study-End of 8th 16th 24th week

Method of measurement

Laboratory biochemical tests

5

Description

uric acid

Timepoint

At the beginning of the study-End of 8th 16th 24th week

Method of measurement

Laboratory biochemical tests

6

Description

Na

Timepoint

At the beginning of the study-End of 8th 16th 24th week

Method of measurement

Laboratory biochemical tests

7

Description

Potassium

Timepoint

At the beginning of the study-End of 8th 16th 24th week

Method of measurement

Laboratory biochemical tests

Intervention groups

1

Description

Intervention group: The group that takes Empagliflozin tablets 10 mg daily for 24 weeks

Category

Treatment - Drugs

2

Description

Control group: The group that takes Placebo(lactose monohydrate) tablets daily for 24 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Fatemeh Jalali

Street address

Shariati hospital, North Kargar Street, Jalal AlAhmad Highway

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Fax

+98 21 8863 3039

Email

shariatihosp@tums.ac.ir

Web page address

http://Shariati.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Orchidpharmed

Full name of responsible person

Dr Araz Sabzevari

Street address

Number 42, Attar Square, Vanak Square

City

tehran

Province

Tehran

Postal code

1994766411

Phone

+98 21 4347 3000

Fax

+98 21 4347 3000

Email

Info@orchidpharmed.com

Web page address

http://Orchidpharmed.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Orchidpharmed

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

Industry

Email

shariatihosp@tums.ac.ir

Web page address

http://Shariati.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fattemeh Jalali

Position

flowship

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Shariati hospital, North Kargar Street, Jalal AlAhmad Highway

City

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+98 21 8490 1000

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+98 21 8863 3039

Email

shariatihosp@tums.ac.ir

Web page address

http://shariati.tums.ac.ir

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Jalali

Position

flowship

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Email

shariatihosp@tums.ac.ir

Web page address

<http://shariati.tums.ac.ir>

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 further 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

Not applicable

Data Dictionary

Not applicable