Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 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
Inclution 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 Exclution 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
fattemeh jalali khalil abadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8490 1000

Email address
fattemeh.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 filteration 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

Potasium

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 Empagloflozin tablets 10 mg daily for 24 weeks

Category

Treatment - Drugs

2

Description

Control group: The group that takes Plasebo(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

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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

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Tehran

Postal code
1994766411

Phone
+98 21 4347 3000

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+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

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

Street address
Shariati hospital, North Kargar Street, Jalal AlAhmad Highway

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

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Web page address

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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 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