

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

A study to assess the safety and tolerability of the SGLT2 inhibitor empagliflozin on proteinuria in non-diabetic patients

Protocol summary

Study aim

Evaluation of tolerance and safety of empagliflozin in children with non-diabetic proteinuria

Design

The current study is a phase 1 clinical trial study and will be conducted in children with non-diabetic proteinuria aged 5 to 17 years. In this study, patients will receive the usual treatment regimen along with Empagliflozin at the beginning with a dose of 5 mg for 3 months and then 10 mg per day for another 3 months (for a total of 24 weeks). This study is a study. It is a pilot and the data collection method is laboratory, observation and interview, and the collection tool will be a questionnaire, and the resulting data will be evaluated using SPSS software.

Settings and conduct

This study is a clinical trial and is conducted at Ali Asghar Children's Hospital.

Participants/Inclusion and exclusion criteria

- Study population: 1-1- Criteria for entering the study: 1- Age 5 to 17 years 2- Suffering from non-diabetic proteinuria according to the diagnosis of a nephrologist 3- Receiving a clinically appropriate dose of ACEIs or ARBs unless the treatment is intolerable or has no indication. 4- GFR more than 60 ml/min 1-2- Exclusion criteria from the study: 1- Suffering from moderate to severe liver failure 2- Type 1 and 2 diabetes 3- Allergy to any component of the drugs used 4- Hypotension 5- Receiving immunosuppressants during the last 6 months 6- Polycystic kidney disease 7- Poor compliance of the patient during the visits regarding the drugs used 8- Kidney transplant 9- Simultaneous reception of ACEIs or ARBs

Intervention groups

After entering the study, patients will be treated with the usual treatment regimen plus empagliflozin at a daily dose of 5 mg for 12 weeks. Then, if tolerated, the dose will be increased to 10 mg per day and the treatment will continue for another 3 months (24 weeks in total).

Main outcome variables

Change in eGFR Change in weight Changes in blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220405054414N1**

Registration date: **2023-08-27, 1402/06/05**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-27, 1402/06/05**

Update count: **0**

Registration date

2023-08-27, 1402/06/05

Registrant information

Name

Mohammadreza Maghamipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4447 5019

Email address

mmaghmi11@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-30, 1402/02/10

Expected recruitment end date

2024-04-29, 1403/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A study to assess the safety and tolerability of the SGLT2 inhibitor empagliflozin on proteinuria in non-diabetic patients

Public title
The effect of empagliflozin on proteinuria

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 5 to 17 years old Suffering from non-diabetic proteinuria according to the diagnosis of a nephrologist Receiving a clinically appropriate dose of ACEIs or ARBs unless treatment is not tolerated or indicated GFR more than 60ml/min
Exclusion criteria:
Moderate to severe liver failure Having type 1and 2 diabetes Sensitivity to any of the components of the drugs used Hypotension Receiving immunosuppressants in the last 6 months Having Polycystic kidney disease Poor patient compliance during medication visits Kidney transplant Concurrent administration of ACEIs or ARBs

Age
From **5 years** old to **17 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran university of medical sciences
Street address

Iran medical university, Hemmat highway, milad tower
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2023-04-26, 1402/02/06
Ethics committee reference number
IR.IUMS.REC.1402.050

Health conditions studied

1

Description of health condition studied
Proteinuria
ICD-10 code
R80.1
ICD-10 code description
Persistent proteinuria, unspecified

Primary outcomes

1

Description
change in body measurement
Timepoint
baseline to 24 weeks
Method of measurement
scales

2

Description
change in blood pressure
Timepoint
baseline to 24 weeks
Method of measurement
Pressure gauge device

3

Description
change in eGFR
Timepoint
baseline to 24 weeks
Method of measurement
schwartz method

4

Description
change in glycemic control
Timepoint
baseline to 24 weeks
Method of measurement
blood draw from vein

5

Description

time to the first occurrence of urinary infection

Timepoint

baseline to 24 weeks

Method of measurement

urine analysis

6

Description

time to first occurrence of AKI

Timepoint

baseline to 24 weeks

Method of measurement

SCr

Secondary outcomes

1

Description

Change from baseline in proteinuria

Timepoint

Baseline to 24 weeks

Method of measurement

Urin analysis

Intervention groups

1

Description

Intervention group: All non-diabetic proteinuria patients aged 5 to 17 years are first given half a tablet of empagliflozin 10 mg (Gloripa manufactured by Abidi company) for 3 months, and if they tolerate it for another 3 months, they are given a full tablet .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Asghar hospital

Full name of responsible person

Mohammadreza Maghamipour

Street address

Ali Asghar hospital , Zafar Ave

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

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Email

mmaghani11@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mohammadreza Maghamipour

Street address

Pharmacy school, Besarati street, kabiri avenue, Hemmat highway

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1475886671

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mmaghani11@yahoo.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Financial source is private

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mohammadreza Maghamipour

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Parastoo Mirzabeigi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
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pmirzabeygi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohammadreza Maghamipour
Position
Student
Latest degree
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Other areas of specialty/work
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mmaghami11@yahoo.com

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

No - There is not 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 collected deidentified IPD

When the data will become available and for how long

One year after publication

To whom data/document is available

available for people working in academic institute

Under which criteria data/document could be used

Using the information by the principle investigators for the use in other research work

From where data/document is obtainable

Parastoo Mirzabeygi pmirzabeygi@gmail.com

What processes are involved for a request to access data/document

1 year after publication, the principal investigator of the other studies with academic position can request for data sharing from the principal investigator of the current study

Comments