Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

mmaghami11@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 ۲۴ 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
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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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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 updating data

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Email
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 oh the other studies with academic position can request for data sharing from the principal investigator of the current study
Comments