Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of empagliflozin and metformin with Melijent and metformin in chronic kidney failure patients

Protocol summary

Study aim
Determining the effect of empagliflozin and metformin with melijent and metformin in diabetic chronic kidney failure patients

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 150 patients. The rand function of Excel software was used for randomization.

Settings and conduct
Patients with chronic kidney failure and diabetes referred to Imam Hossein (AS) hospital in 1402. This study is double-blind. The drugs needed for the people participating in the study will be sent to the treatment center from the manufacturing company in a completely covered and indistinguishable form for use by patients. The people participating in the study and the person in charge of data analysis will not be aware of the division of empagliflozin and melijent group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients over 18 years old Patients with renal function above 20 ml/min (calculated by the MDRD formula) at the first visit Patients with renal function below 60 ml/min (calculated by the MDRD formula) at the first visit Exclusion criteria: -Frequent UTI - Class (NYHA) IV congestive heart failure at first visit - Myocardial infarction, unstable angina, stroke - Pregnancy and breastfeeding

Intervention groups
Intervention group one: administration of metformin + empagliflozin Intervention group two (active control): administration of metformin + melijent

Main outcome variables
proteinuria, cardiac complications, kidney function, fasting sugar

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230607058409N1**
Registration date: **2023-06-15, 1402/03/25**
Registration timing: **prospective**

Last update: **2023-06-15, 1402/03/25**
Update count: **0**

Registration date
2023-06-15, 1402/03/25

Registrant information
Name
Reza Zeinabadinoghabi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 51 3513 1857
Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-22, 1402/04/01

Expected recruitment end date
2023-12-22, 1402/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of empagliflozin and metformin with Melijent and metformin in chronic kidney failure patients

Public title
Investigating the effect of empagliflozin and melijent in chronic kidney failure patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
-Patients with over 20mL/min/1.73m2 (calculated by MDRD formula) in the first visit Patient over 18 years old patients -Patients with less 60 ml /min/1.73m2 (calculated by MDRD formula) in the first visit
Exclusion criteria:
Class four congestive heart failure Recurrent urinary infection Myocardial infarction, stroke, transient ischemic attack
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling method is convinient and based on the block randomization (Double block)method, individually and using the Rand function of Excel software eligible patients will be divided into two treatment groups according to the determined plan (RCT plan). All people eligible to enter the study will be randomly assigned to one of the two drug receiving groups with a ratio of 1:1.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is double-blind. The drugs needed for the people participating in the study will be sent to the treatment center from the manufacturing company in a completely covered and indistinguishable form for use by patients. All drugs (empagliflozin and Melijent) are similar in shape and color and are taken daily. The people participating in the study and the person in charge of data analysis will not be aware of the division of empagliflozin and melijent group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
دانشگاه علوم پزشکی شهید بهشتی
Secondary trial Id
ir.sbmu.msp.rec.1402.113
Registration date
2023-06-10, 1402/03/20

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Imam Hossein Hospital, Shahid Madani St
City
tehran
Province
Tehran
Postal code
1617763141
Approval date
2023-06-10, 1402/03/20
Ethics committee reference number
ir.sbmu.msp.rec.1402.113

Health conditions studied

1

Description of health condition studied
Diabetic patients
ICD-10 code
E11.2
ICD-10 code description
Type 2 diabetes mellitus with kidney complications

Primary outcomes

1

Description
1) Examination of renal function (GFR)
Timepoint
The effect of improving the renal function of GFR at the beginning of the study (before the start of the intervention) 3 and 6 months after the start of the drugs
Method of measurement
140-Age*weight/ creatinine plasma*72

2

Description
The amount of proteinuria
Timepoint
The amount of proteinuria at the beginning of the study (before the start of the intervention) 3 and 6 months after the start of the drugs
Method of measurement
24-hour proteinuria (mg/dl)

Secondary outcomes

1

Description
Blood pressure
Timepoint
Blood pressure at the beginning of the study (before the start of the intervention) 3 and 6 months after the start of the drugs
Method of measurement
Mercury pressure gauge

2

Description
Fasting sugar
Timepoint
Fasting blood sugar levels at the beginning of the study (before the start of the intervention) 3 and 6 months after the start of the drugs
Method of measurement
Fasting blood sugar test (mg/dl)

Intervention groups

1

Description
When the researcher ensures that the candidate is suitable for entering the study according to all the inclusion and non-entry criteria, the candidate will be placed in one of the following 2 intervention groups based on the predetermined random plan; To ensure acceptance and safety, the drug will be prescribed by an internal specialist. Intervention group one: administration of metformin + empagliflozin Patients in both groups will be followed up for a maximum of 6 months in three occasions (one, three and 6 months after the intervention) during the study. All the results of the study will be reviewed and recorded at zero (before the start of the study (drug administration)) and monthly until the end of 6 months after receiving the intervention (one, three, 6 months after the intervention).Patients treated with empagliflozin 10 mg which are manufactured by Obeidi company.
Category
Treatment - Drugs

2

Description
Intervention group: When the researcher ensures that the candidate is suitable for entering the study according to all the inclusion and non-entry criteria, the candidate will be placed in one of the following 2 intervention groups based on the predetermined random plan; To ensure acceptance and safety, the drug will be prescribed by an internal specialist. Intervention group one: administration of metformin + empagliflozin, intervention group two (active control): administration of metformin + Patients in both groups will be followed up for a maximum of 6 months in three occasions (one, three and 6 months after the intervention) during the study. All the results of the study will be reviewed and recorded at zero (before the start of the study (drug administration)) and monthly until the end of 6 months after receiving the intervention (one, three, 6 months after the intervention)with melijent 5 mg, both of which are manufactured by Obeidi company.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital, Tehran
Full name of responsible person
reza zeinabadi noghabi
Street address
Shahid Madani Street, Imam Hossein Hospital
City
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Shahid Beheshti University of Medical Sciences
Street address
Heran - Valenjak - Shahid Shahriari Square - Student Blvd - Shahid Arabi Street - Shahid Beheshti University of Medical Sciences
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1985717443
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
reza zeinabadi noghabi
Position
Internal resident
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
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Position
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Person responsible for updating data

Contact
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Shahid Beheshti University of Medical Sciences
Full name of responsible person
reza zeinabadi noghabi
Position
internal resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
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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
Yes - There is 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
Potential data can be shared after de-identifying individuals
When the data will become available and for how long
The access period begins 6 months after the results are published.
To whom data/document is available
It will be available only to researchers working in academic and scientific institutions
Under which criteria data/document could be used
It will be available only to researchers working in academic and scientific institutions
From where data/document is obtainable
Imam Hossein Hospital Research and Research Unit We

will respond to the postal address of Imam Hossein Hospital 617763141 or through the researcher's e-mail rezaappleapp@gmail.com.

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

The request should be sent to the researcher's email (Rezaappleapp@gmail.com)

Comments