Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparison the effects of Empaglifluzin-linagliptin and Dapaglifluzin-linagliptin on HbA1c ، LDL and Albuminuria in patients with T2DM

Protocol summary

Study aim

If the results of this study can show the effect of one of the two drugs on reducing HbA1c, LDL and albuminuria better than the other drug, that drug can be used as the preferred drug for treating diabetes complications and also reducing blood sugar.

Design

Randomized parallel clinical trial, single blind, randomized, phase 2 on 70 patients. Randomized block permutation method will be used for randomization.

Settings and conduct

The randomized clinical trial is aligned and the two groups remain constant in terms of intervention until the end of the study. Information will be collected in the outpatient clinics of Amir al-Mominin and Imam Reza Arak hospitals and within 3 months after obtaining the code of ethics. The study is one-sided blind. The researcher and the patient know about the received treatment and there is no possibility of blinding them, but in order to prevent bias in the analysis, the analyst will not know about the treatment group codes to which the patients belong.

Participants/Inclusion and exclusion criteria

Age above 30 and less than 75 years. Having type 2 diabetes. Glycosylated hemoglobin higher than 7.5 and less than 11. Has albuminuria. No acute hospitalization conditions. Not taking medication beforehand.

Intervention groups

Intervention is done in both groups. Empagliflozin-linagliptin is given to one group and dapagliflozin-linagliptin to the other group once a day for three months.

Main outcome variables

The main outcome of this study is urine microalbuminuria, which is considered as the main indicator of diabetic nephropathy, HbA1c and LDL. It is evaluated by urine and blood samples at the beginning of the study, three months after the start of the treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221221056889N1**
Registration date: **2023-02-23, 1401/12/04**
Registration timing: **prospective**

Last update: **2023-02-23, 1401/12/04**
Update count: **0**

Registration date

2023-02-23, 1401/12/04

Registrant information

Name

Saeed Seyedi niasar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7755 1763

Email address

sseyedi43@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-06, 1401/12/15

Expected recruitment end date

2023-07-06, 1402/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of Empaglifluzin-linagliptin and Dapaglifluzin-linagliptin on HbA1c ، LDL and Albuminuria in patients with T2DM

Public title
Comparison the effects of Empaglifluzin-linagliptin and Dapaglifluzin-linagliptin on HbA1c ، LDL and Albuminuria in patients with T2DM

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having type 2 diabetes Hb A1c above 7 and below 11 No acute hospitalization conditions Age between 30 and 75 years Patients with albuminuria Not taking the drug beforehand

Exclusion criteria:
Acute hospitalization conditions Pre-medication

Age
From **30 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, permutation random block method will be used for randomization. For this purpose, a block of 6 will be used. In each block, the letter E is written on 3 cards and the letter D is written on 3 cards. The random blocks of 6 chosen are as follows: ,DEDDEE,DEEDDE,EDEDED,DEEDDE,EEDEDD,EDEDDE .EDDE, DEDDEE, EEDEDD, EDDEED, DEEDDE, EDDDEE (For example, the method of random assignment in EDEDDE block of 6 is as follows: the first patient to treatment E, the second patient to treatment D, the third patient to treatment E, the fourth patient to treatment D, the fifth patient to treatment D, and the sixth patient to Treatment E is randomly assigned.) The purpose of randomization is to create homogenous groups, so by randomizing, groups will be formed that are similar to a large extent in terms of many influencing characteristics, and the only factor that differs between groups is the treatment that they have been randomly assigned to, and thus it can be He said that the result observed in each group is the effect of that drug and in fact the effectiveness of the drug can be estimated.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is single-blind. In this way, the researcher and the patient know about the received treatment and there is no possibility of blinding them, but in order to prevent bias in the analysis, the analyst will not know about the codes of the treatment group to which the patients belong.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Arak University of Medical Sciences

Street address
sardasht

City
Arak

Province
Markazi

Postal code
6341738481

Approval date
2022-12-25, 1401/10/04

Ethics committee reference number
IR.ARAKMU.REC.1401.292

Health conditions studied

1

Description of health condition studied
Type 2 diabetes

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The main outcome of this study is urine microalbuminuria, which is considered as the main indicator of diabetic nephropathy, LDL and HbA1c. This result is evaluated by spot urine and blood samples at the beginning of the study, three months after the start of the treatment.

Timepoint
At the beginning of the study and three months after the start of treatment

Method of measurement
It is evaluated by spot urine and blood samples at the beginning of the study and three months after the start of the treatment

Secondary outcomes

1

Description
Other outcomes included in the researcher's checklist (attached at the end of the proposal), such as FBS, GFR, and lipid profile, are evaluated by the patient's blood test at the beginning of the study, and after the completion of the treatment period, i.e., three months after the start of the treatment.

Timepoint
The beginning of the study and three months after the start of treatment

Method of measurement
By testing the patient's blood.

Intervention groups

1

Description
First intervention group: empagliflozin-linagliptin drug 5-10 mg daily and one tablet per day for three months. The second intervention group: dapagliflozin-linagliptin 5-10 mg daily, one tablet per day for three months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Outpatient clinics of Amir al-Mominin and Imam Reza hospitals in Arak city

Full name of responsible person
Saeed seyedi niasar

Street address
Sardasht - Basij Square - Amirul Mominin Hospital

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https://chat.whatsapp.com/CSQamAC5uaYDO1wcfluTt1

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Dr. Mehdi Salehi

Street address
Shahid Shiroodi St. - Alam El Hoda St

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Web page address
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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Saeed seyedi niasar

Position
Internal resident

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

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Sardasht - Basij Square - Amirul Mominin Hospital - internal group training

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Person responsible for scientific inquiries

Contact

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Medical doctor

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Person responsible for updating data

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Internal resident

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available