# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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

**City**
Arak

**Province**
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3848176941

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it-amiralmomenin@arakmu.ac.ir

**Web page address**
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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info@arakmu.ac.ir

**Web page address**
https://arakmu.ac.ir/

**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

**Street address**
Sardasht - Basij Square - Amirul Mominin Hospital - internal group training

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**
Internal resident

**Latest degree**
Medical doctor

**Other areas of specialty/work**
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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