# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

12 Jun 2026

## Comparison of the Effect of Empaglifluzin and Linagliptin on the Albuminuria of patients with diabetes mellitus type 2 patients

### Protocol summary

**Study aim**

Comparison of the mean amount of albuminuria between the group receiving Empagliflozin with the group receiving Linagliptin at the beginning and end of the study

**Design**

This study is a double blind clinical trial in which 60 patients in two groups receive a random code, which corresponds to the numbers on the sealed envelopes. The first group will be given 10 mg daily of Empagliflozine and the second group will be given 5 mg of Linagliptin daily for 90 days. It will be examined on microalbuminuria at the beginning and end of the study.

**Settings and conduct**

This study is a parallel randomized clinical trial. The study site will be Amir Al-Momenin Hospital in Arak and the duration of patient monitoring will be ninety days from the start of the drug recommendation. Blinding of patients by identifying drug packages and collector by separating checklist header information will be done.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Age over 30 years old and under 75 years old Type 2 diabetes The patient has microalbuminuria Exclusion criteria: HbA1C> 9%. Uncontrolled hypertention Uncontrolled blood sugar Heart failure Chronic liver disease GFR lower than 30 Existence of hematuria Signs of active urinary tract and kidney infection Having a urinary catheter To be in nephropathy stages 3 or next stages Other kidney diseases that cause albuminuria such as glomerulonephritis Acute hospital conditions

**Intervention groups**

This clinical trial was designed in two groups of 30 people. For one group, Empagliflozin 10 mg and for the other group 5 mg Linagliptin daily It will be given for 90 days.

**Main outcome variables**

The main outcome of the study on microalbuminuria, which is the main indicator of diabetic nephropathy, is evaluated by a random urine sample before treatment and at the end of the study period. Other Outcomes: Hba1c, FBS, GFR, and patients lipid profile.

### General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20200722048176N1**
Registration date: **2020-08-03, 1399/05/13**
Registration timing: **prospective**

Last update: **2020-08-03, 1399/05/13**
Update count: **0**

**Registration date**

2020-08-03, 1399/05/13

**Registrant information**

**Name**

Mohammad Amin Mohammadzadeh Gharabaghi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 86 3417 3630

**Email address**

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-09-01, 1399/06/11

**Expected recruitment end date**

2021-07-01, 1400/04/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the Effect of Empaglifluzin and Linagliptin on the Albuminuria of patients with diabetes mellitus type 2 patients

**Public title**

Comparison the Effect of Empaglifluzin and Linagliptin on the Albuminuria of diabetic patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age over 30 years and under 75 years Type 2 diabetes The patient has microalbuminuria

**Exclusion criteria:**

HbA1C>9% uncontrolled blood pressure uncontrolled blood sugar heart failure chronic liver disease GFR<30 presence of hematuria signs of active urinary and renal infection uinary catheter High stages of nephropathy other kidney diseases that cause albuminuria such as glomerulonephritis acute hospital conditions

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization method of this study is performed according to the random allocation rule, by first preparing a uniform and sealed envelope based on the total samples and an equal number of samples of each group, inside the envelopes on which the number one are written for the first intervention group and the number two are written for the second intervention group and patients randomly pick up an envelope when entering the study and allocate based on the numbers in the envelopes.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, both the patient and the person entering the information into the checklist do not know what group the patient is in. The study is a double-blind study. Participants are blinded by identifying the shape of the drugs and similar packaging. To blind the data collector, the checklist header is removed so that it is not clear to which group the patient belongs.

**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**

Internal medicine group,Amiralmomenin Hospital,Sardasht,Arak,Iran

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Approval date**

2020-06-28, 1399/04/08

**Ethics committee reference number**

IR.ARAKMU.REC.1399.127

## Health conditions studied

**1**

**Description of health condition studied**

Diabetic Nephropathy

**ICD-10 code**

E11.21

**ICD-10 code description**

Type 2 diabetes mellitus with diabetic nephropathy

## Primary outcomes

**1**

**Description**

Comparison of mean albuminuria between the group receiving Empagliflozin with the group receiving Linagliptin at the beginning and end of the study

**Timepoint**

At the beginning of the study and ninety days after starting the drug

**Method of measurement**

Measurement of urinary microalbumin exceretion sampling

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
For patients in the first intervention group, 10 mg of Empagliflozin (manufactured by Dr. Abidi Pharmaceutical Company under the brand name Gloripa) is administered orally once daily for ninety days or three months.
**Category**
Treatment - Drugs

### 2

**Description**
For patients in the second intervention group, Linagliptin 5 mg (manufactured by Dr. Abidi Pharmaceutical Company under the brand name Lirenta) is administered orally once daily for ninety days or three months.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Amiralmomenin Hospital
**Full name of responsible person**
Mohammad Amin Mohammadzadeh Gharebaghi
**Street address**
Sardasht,Arak
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3848176941
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Arak University of Medical Sciences
**Full name of responsible person**
معاونت تحقیقات و فناوری
**Street address**
Internal medicine group,Amiralmomenin Hospital,Sardasht,Arak
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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**
Mohammad Amin Mohammadzadeh Gharabaghi
**Position**
Resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Internal Medicine
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## Person responsible for scientific inquiries

**Contact**
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**Position**
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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

Internal Medicine

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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