Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

amin@arakmu.ac.ir

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
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3417 3630
Email
amin@arakmu.ac.ir

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
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3417 3645
Email
amin@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
Mohammad Amin Mohammadzadeh Gharabaghi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
Arak,Sardasht,Amiralmomenin hospital,Internal medicine group
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3417 3630
Fax
Email
amin@arakmu.ac.ir

Person responsible for scientific 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

Street address

Arak,Sardasht,Amiralmomenin hospital,Internal medicine group

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3630

Fax

Email

amin@arakmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Amin Mohammadzadeh Gharabaghi

Position

Resident

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+98 86 3417 3630

Fax

Email

amin@arakmu.ac.ir

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