

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Evaluation the effect of Linagliptin and Empagliflozin combination on glycosylated hemoglobin and fasting blood sugar control in patients with type 2 diabetes

Protocol summary

Study aim

determining the effect of the combination of Linagliptin and Empagliflozin on the control of glycosylated hemoglobin and fasting blood sugar in patients with type 2 diabetes

Design

Semi-experimental clinical trial, without control group, without blinding, without randomization, phase 2, on 55 patients.

Settings and conduct

Diabetic patients attended to the endocrinology clinic of Amir al-Mominin Hospital and Imam Reza Clinic who did not respond properly to other oral treatments. They also received oral medicine in a suitable period of time, but the appropriate response in reducing hba1c was not satisfactory.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who are diagnosed with type 2 diabetes based on ADA diagnostic criteria and have medical treatment indications Patients who have not reached the treatment goals despite receiving previous medications (HbA1c) more than 7 and FBS (more than 130). exclusion criteria: Type 1 diabetes pregnancy Diabetic ketoacidosis (current and previous history) Pancreatitis (current and previous history) Diabetic foot ulcer (current and previous history) GFR less than 30 BMI less than 18.5 The occurrence of severe drug side effects for the patient Lack of consent to participate in the study untreated Urinary Tract Infection {UTI}

Intervention groups

Patients will receive the combination of linagliptin and empagliflozin

Main outcome variables

HBA1C; FBS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221016056201N1**

Registration date: **2023-02-08, 1401/11/19**

Registration timing: **prospective**

Last update: **2023-02-08, 1401/11/19**

Update count: **0**

Registration date

2023-02-08, 1401/11/19

Registrant information

Name

Mohammad Davari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3477 8386

Email address

buccynator@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-09, 1401/11/20

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of Linagliptin and Empagliflozin combination on glycosylated hemoglobin and fasting blood sugar control in patients with type 2 diabetes

Public title

Effect of Linagliptin and Empagliflozine on diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients who have been diagnosed with type 2 diabetes mellitus based on the ADA diagnostic criteria and indicated for medical therapy patients who have not reached to treatment goals despite receiving previous medications

Exclusion criteria:

type 1 diabetes pregnancy diabetic ketoacidosis (present and previous) pancreatitis (present and previous) diabetic foot ulcer (present and previous) GFR less than 30 BMI less than 18.5 severe adverse drug reactions lack of consent to participate in the study untreated urinary tract infection

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 55

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committees of Arak University of Medical Sciences

Street address

Arak University of Medical Science, Arak

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2022-04-02, 1401/01/13

Ethics committee reference number

IR.ARAKMU.REC.1401.004

Health conditions studied

1

Description of health condition studied

Diabetes type 2

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

fasting blood sugar

Timepoint

beginning of the study, 3 months later

Method of measurement

blood sample

Secondary outcomes

1

Description

glycosylated hemoglobin

Timepoint

beginning of the study, 3 months later

Method of measurement

blood sample

Intervention groups

1

Description

Intervention group: type 2 diabetic patients resistant to other oral anti-diabetic treatments (metformin, glybenclamide and acarbose) whose FBS and HbA1C are not within the therapeutic range despite regular use of these drugs. These patients receive the combination of empagliflozin and linagliptin daily for 3 months, then their FBS and HbA1C will be measured again and compared with their baseline FBS and HbA1C on the first day of the study. Patients will be taught to take one empagliflozin and linagliptin combination tablet daily during these three months and to adhere to this method of use.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir-al Momenin hospital

Full name of responsible person

Mohammad Davari

Street address

Sardasht, Amir-al-momenin Hospital

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3836 2221

Email

buccynator@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mehdi Salehi

Street address

Sardasht, Amir-al-momenin Hospital

City

Arak

Province

Markazi

Postal code

3848176341

Phone

+98 86 3417 3639

Email

research@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 Davari

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Sardasht, Amir-al-momenin Hospital

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3836 2221

Email

buccynator@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Davari

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Sardasht, Amir-al-momenin Hospital

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3836 2221

Email

buccynator@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Davari

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Sardasht, Amir-al momenin hospital

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3836 2221

Email

buccynator@gmail.com

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