

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

The evaluation of the effect of linagliptin on microalbuminuria in type 2 diabetes patients with nephropathy

Protocol summary

Study aim

Determination of the effect of linagliptin on microalbuminuria in type 2 diabetes patients with nephropathy

Design

A clinical trial with a parallel control group, double blind, randomized

Settings and conduct

This double blind clinical trial (researchers and participants) will be performed on 80 people (≥ 18 years old) with type 2 diabetes with microalbuminuria referring to the Isfahan Endocrine and Metabolism Research Center. Patients will enter this study in terms of entry and exit criteria and obtain consent form. Patients will be evaluated two weeks after the start of the study and then every 4 weeks to evaluate the side effects of the drug. Anthropometric, biochemical and blood pressure variables are evaluated using standard methods at the beginning of the study, 12 and 24 weeks after the start of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with 6.5% to 10% glycated hemoglobin (hemoglobin HbA1c) (48 to 86 mmol / mol); patients with Body Mass Index ≤ 40 kg / m²; the level of albumin to creatinine (UACR) ranged from 30 to 3000 mg / g creatinine (in three urine samples consecutive two weeks before the start of the study). Exclusion criteria: patients who consumed rapid acting insulin, rosiglitazone, pioglitazone, GLP-1 analogues, or anti-obesity drugs three months before the start of the study; patients who had myocardial infarction, stroke, or transient ischemic attack six months before the start of the study; patients with non-diabetic renal insufficiency or urinary tract infection; patients who have received kidney transplants.

Intervention groups

Patients will randomly be divided into one of two groups of drug (5 mg laggliptin) or placebo.

Main outcome variables

Blood pressure; urine Albumin-to-Creatinine ratio

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171030037093N11**

Registration date: **2019-05-08, 1398/02/18**

Registration timing: **prospective**

Last update: **2019-05-08, 1398/02/18**

Update count: **0**

Registration date

2019-05-08, 1398/02/18

Registrant information

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Sadra Ansari pour

Name of organization / entity

Shahrekord University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-20, 1398/02/30

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of the effect of linagliptin on microalbuminuria in type 2 diabetes patients with nephropathy

Public title

The effect of linagliptin on microalbuminuria in diabetes patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with 6.5% to 10% glycated hemoglobin (hemoglobin HbA1c) (48 to 86 mmol / mol) Patients with BMI ≤ 40 kg / m² The level of albumin to creatinine (UACR) ranged from 30 to 3000 mg / g creatinine (in three urine samples consecutive two weeks before the start of the study)

Exclusion criteria:

Patients who consumed rapid acting insulin, rosiglitazone, pioglitazone, GLP-1 analogues, or anti-obesity drugs three months before the start of the study Patients who had myocardial infarction, stroke, or transient ischemic attack six months before the start of the study. Patients with non-diabetic renal insufficiency or urinary tract infection Patients who have received kidney transplants

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Cases are randomized using random allocation through the software. In this way, after the selection of 80 people that have the inclusion criteria, people are randomly assigned to one of the two intervention groups by statistical software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drugs were packaged in the same package by the pharmacist, and none of the patients and researchers knew about their contents.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahn University of Medical Sciences, Hezar jarib st, Isfahan

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Postal code

7346181746

Approval date

2018-09-26, 1397/07/04

Ethics committee reference number

IR.MUI.MED.REC.1397.230

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**

Urine Albumin-to-Creatinine Ratio

Timepoint

In three urine samples collected consecutively two weeks before the start of the study and two weeks after the start of the study and then every 4 weeks

Method of measurement

Experiments

2**Description**

Blood pressure

Timepoint

At the beginning of the study, 12 and 24 weeks after the start of the intervention

Method of measurement

measurement

Secondary outcomes

1

Description

body mass index

Timepoint

At the beginning of the study, 12 and 24 weeks after the start of the intervention

Method of measurement

measurement

2

Description

Level glycosylated hemoglobin

Timepoint

At the beginning of the study, 12 and 24 weeks after the start of the intervention

Method of measurement

Experiments

3

Description

Glomerular filtration rate (GFR)

Timepoint

At the beginning of the study, 12 and 24 weeks after the start of the intervention

Method of measurement

MDRD formula

4

Description

Liver Enzymes (ALT, AST, ALP)

Timepoint

At the beginning of the study, 12 and 24 weeks after the start of the intervention

Method of measurement

Experiments

5

Description

Profile Lipid (TG, LDL, HDL, total cholesterol)

Timepoint

At the beginning of the study, 12 and 24 weeks after the start of the intervention

Method of measurement

Experiments

Intervention groups

1

Description

Intervention group: A group treated with lagglyptin 5 mg for 24 weeks.

Category

Treatment - Drugs

2

Description

Control group: A group treated with placebo for 24 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Isfahan Endocrine and Metabolism Research Center

Full name of responsible person

Ashraf Aminorroaya

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Isfahan Endocrine and Metabolism Research Center, Amin Medical Center, Ebnesina Ave., Shohada Square, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Ziba Farajzadegan

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Ashraf Aminorroaya

Position

professor

Latest degree

Subspecialist

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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Information about the main outcome can be shared.

When the data will become available and for how long

Start the access period 4 months after publishing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Use data to complete clinical trial studies

From where data/document is obtainable

Department of Physical Medicine and Rehabilitation
What processes are involved for a request to access data/document

after the investigation of researcher request and presentation of required documents will be accessible.
Comments