Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Linagliptin on Proteinuria in Diabetic Renal Disease patients

Protocol summary

Study aim
Effect of Linagliptin on proteinuria in diabetic patients with chronic kidney disease
Design
Randomized double blinded clinical trial with a parallel group design of 140 patients, enrolled between March 2019 and May 2020
Settings and conduct
All allocated participants are enrolled in study, after filling satisfaction in a hospital & a private clinic. they receive drug or placebo blindly.
Participants/Inclusion and exclusion criteria
Inclusion: Have Diabetes Mellitus, eGFR between 30-60cc/min/1.73m2 , Proteinuria more than 300mg/d , Not use Immunosuppressive drugs(cyclosporin, tacrolimus, mycophenolate, azathioprin, methotrexate), inactive urine sediment Exclusion: Changes in drug doses of proteinuria like Angiotensin converting enzyme inhibitors, Angiotensin receptor blockers, Diltiazem, statins, Drug complications like cough, sore throat, myalgia and uncooperative patients
Intervention groups
Patients are taken Linagliptin 5 mg manufactured by Alhavi pharmaceutics for 6 months. they do laboratory examination at months 3 & 6. patients in control group are taken placebo drug, manufactured by Alhavi pharmaceutics and do laboratory examination after months 3 & 6.
Main outcome variables
proteinuria ؛ Creatinin ؛ systolic blood pressure ؛ diastolic blood pressure ؛ HbA1C

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20090905002417N23**
Registration date: **2020-02-01, 1398/11/12**
Registration timing: **registered_while_recruiting**
Last update: **2020-02-01, 1398/11/12**
Update count: **0**
Registration date
2020-02-01, 1398/11/12

Registrant information
Name
Firouzeh Moeinzadeh
Name of organization / entity
Isfahan University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-03-21, 1398/01/01
Expected recruitment end date
2020-06-19, 1399/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Linagliptin on Proteinuria in Diabetic Renal Disease patients

Public title
Effect of Linagliptin on diabetic proteinuria
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diabetes Mellitus eGFR between 30-60cc/min/1.73m2

Proteinuria more than 300mg/d Not use Immunosuppressive drugs(cyclosporin, tacrolimus, mycophenolate, azathioprin, methotrexate) inactive urine sediment

Exclusion criteria:

Hypoglycemia HbA1C less than 6%

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

The numbers are divided to 2 groups: study and placebo according to table of random numbers via software. this numbers have 4 parts. First participate receive first 4 digit number, second person receive second 4 digit number and .....They receive drug or placebo according to codes. The study is a double blind because the patients and coordinator do not know there is drug or placebo. Principal investigator design random numbers and get to coordinator. Only principal investigator know which package is drug or placebo and he do not have any role in data analysis.It is a double blind study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drug & placebo will be given to care provider. these drugs are similar together and are given to participant. care provider & participant are blinded about drug

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

Sofe Ave. Isfahan Kidney Diseases Research Center, Isfahan, Iran.

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2018-09-02, 1397/06/11

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.196

Health conditions studied

1

Description of health condition studied

Proteinuria in diabetic patients with chronic kidney disease

ICD-10 code

E08.22

ICD-10 code description

Diabetes mellitus due to underlying condition with diabetic chronic kidney disease

Primary outcomes

1

Description

proteinuria

Timepoint

before intervention and 3 & 6 months later

Method of measurement

urine 24 hours collection

Secondary outcomes

1

Description

serum creatinin

Timepoint

before intervention and 3 & 6 months later

Method of measurement

laboratory kit ELISA

2

Description

systolic blood pressure

Timepoint

before intervention and 3 & 6 months later

Method of measurement

Digital sphygmomonometer

3

Description

diastolic blood pressure

Timepoint

before intervention and 3 & 6 months later

Method of measurement
Digital sphygmomonometer

4

Description
Hemoglobin A1C
Timepoint
before intervention and 3 & 6 months later
Method of measurement
laboratory kit ELISA

5

Description
fasting blood suger
Timepoint
before intervention and 3 & 6 months later
Method of measurement
laboratory kit

Intervention groups

1

Description
Intervention group: Linagliptin (Melijent), Linagliptin molecule, 5mg tablet, one tablet daily for 6 months, irrespective to diet, manufactured by Alhavi pharmaceutic, IRAN
Category
Treatment - Drugs

2

Description
Control group: Placebo tablet, 5 mg, daily for 6 months, manufactured by Alhavi pharmaceutic, IRAN
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzaha hospital
Full name of responsible person
Firouzeh Moeinzadeh
Street address
Sofe Ave. Alzahra hospital, Isfahan, Iran.
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Web page address

2

Recruitment center
Name of recruitment center
Private clinic
Full name of responsible person
Mojgan Mortazavi
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Azhand building, Amadegah Av, 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
Dr. Shaghayegh Haghjoy Javanmard
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Phone
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Email
research@mui.ac.ir
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
10
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
Firouzeh Moeinzadeh
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Nephrology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Analyzed data will be available
When the data will become available and for how long
starting 6 months after publication
To whom data/document is available
this only available for people working in academic institutions
Under which criteria data/document could be used
In response to requests via email sending, only analysis and results will send to person via person responsible for scientific inquiries. Using the analysis without reference indicating is forbidden. email: fimoinzad@yahoo.com
From where data/document is obtainable
Requests via email sending to person responsible for scientific inquiries address: fimoinzad@yahoo.com .
What processes are involved for a request to access data/document
After receiving email, it will be responsed
Comments