

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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/1.73m<sup>2</sup>, 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 pharmaceuticals for 6 months. they do laboratory examination at months 3 & 6. patients in control group are taken placebo drug, manufactured by Alhavi pharmaceuticals 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)

###### Phone

+98 31 1625 5555

###### Email address

moinzade@resident.mui.ac.ir

##### 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/1.73m<sup>2</sup>

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**

Isfahan

**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 sphygmomanometer

3

**Description**

diastolic blood pressure

**Timepoint**

before intervention and 3 & 6 months later

**Method of measurement**  
Digital sphygmomanometer

#### 4

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

#### 5

**Description**  
fasting blood sugar  
**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 pharmaceutical, IRAN  
**Category**  
Treatment - Drugs

#### 2

**Description**  
Control group: Placebo tablet, 5 mg, daily for 6 months, manufactured by Alhavi pharmaceutical, 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.  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8174673461  
**Phone**  
+98 31 3822 6713  
**Email**  
fimoinzad@yahoo.com

### Web page address

#### 2

**Recruitment center**  
**Name of recruitment center**  
Private clinic  
**Full name of responsible person**  
Mojgan Mortazavi  
**Street address**  
Azhand building, Amadegah Av, Isfahan, IRAN  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8174673461  
**Phone**  
+98 31 3822 6713  
**Email**  
m\_mortazavi@med.mui.ac.ir

### Sponsors / Funding sources

#### 1

**Sponsor**  
**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Dr. Shaghayegh Haghjoy Javanmard  
**Street address**  
Hezar Jarib Avenue  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8174673461  
**Phone**  
+98 31 3668 8138  
**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

**Street address**

Sofe street, Alzahra hospital

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3822 6713

**Email**

f\_moinzade@med.mui.ac.ir

## Person responsible for scientific 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

**Street address**

Sofe street, Alzahra hospital

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3822 6713

**Email**

fimoinzad@yahoo.com

## Person responsible for updating data

### 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

**Street address**

Sofe street, Alzahra hospital

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3822 6713

**Email**

fimoinzad@yahoo.com

## 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 responded

**Comments**