

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### The evaluation of sitagliptin on proteinuria in diabetic patient with nephropathy.

#### Protocol summary

##### Summary

Objective: Sitagliptin effect on proteinuria in diabetic nephropathy Inclusion criteria: type II diabetes, glomerular filtration rate greater than 30 and proteinuria more than 150 milligrams per deciliter. Exclusion criteria: adverse drug reactions, exacerbation of renal failure and lack of glycemic control defined ranges. Study population: patients referred to the clinics of Nephrology and Endocrinology of Amirmomenin Hospital. Sample size: 49 Intervention: A Case Study Sitagliptin 25 mg daily since the beginning of the second 3 months to the end of the study. The primary outcome: change in proteinuria.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017022532769N1**

Registration date: **2017-06-13, 1396/03/23**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-06-13, 1396/03/23

##### Registrant information

###### Name

Mohammad Ali Ahmadloo

###### Name of organization / entity

Arak University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3223 9226

###### Email address

drahmadloo@irimc.org

##### Recruitment status

**Recruitment complete**

##### Funding source

Arak University of Medical Sciences

##### Expected recruitment start date

2016-08-22, 1395/06/01

##### Expected recruitment end date

2017-07-23, 1396/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The evaluation of sitagliptin on proteinuria in diabetic patient with nephropathy.

##### Public title

Effect of sitagliptin on excretion of protein in diabetic

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: Type 2 of diabet ; glomerular filtration rate more than 30 ; HbA1C 6.5-8.5 ; continue of previous diet , exersize & drug ; proteinuria more than 150mg/dl. Exclusion criteria: Patient do not allow continue of study ; drug adverse reaction ; blood suger more than difined range ; exacerbation of renal failure.

##### Age

No age limit

##### Gender

Both

##### Phase

N/A

##### Groups that have been masked

No information

##### Sample size

Target sample size: **49**

## 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

Arak University of Medical Sciences

#### Street address

Arak University of Medical Sciences - (Basij Sq. Pardis sight Mail Box 1884)

#### City

Arak

#### Postal code

۳۸۴۸۱-۷-۶۹۴۱

### Approval date

2016-08-10, 1395/05/20

### Ethics committee reference number

IR.ARAKMU.REC.1395.148

## Health conditions studied

1

### Description of health condition studied

Diabet type 2

### ICD-10 code

E11.2

### ICD-10 code description

E11.2 Non-insulin-dependent diabetes mellitus with renal complications

## Primary outcomes

1

### Description

Urine protein

### Timepoint

3 mo.before , before & 3 mo. after trial

### Method of measurement

24h urine protein /mg/dl

## Secondary outcomes

1

### Description

Hypoglycemia

### Timepoint

3 month

### Method of measurement

FBS check

## Intervention groups

1

### Description

Sitagliptin 25mg daily oral for 3 month

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Amiralmomenin Hospital

#### Full name of responsible person

Dr.Mohammad Ali Ahmadloo

#### Street address

Arak - sardasht street - basij sq. - Amiralmomenin Hospital

#### City

Arak

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Arak University of Medical Sciences

#### Full name of responsible person

Dr. Mohammad Rafeie

#### Street address

Arak University of Medical Sciences - MOJTAMEH E PAYAMBAR AZAM

#### City

Arak

### 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

empty

### Domestic or foreign origin

empty

### Category of foreign source of funding

empty

**Country of origin**  
**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Dr. Mohammad Ali Ahmadloo  
**Position**  
Internal Medicine Resident of Arak University of Medical Sciences  
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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**  
Dr. Naser Saidi  
**Position**  
Assistant professor of internal medicine (nephrology)  
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**Web page address**

## Person responsible for updating data

### Contact

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**Other areas of specialty/work**  
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**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*