

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

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Name of organization / entity

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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 committees1**Ethics committee****Name of ethics committee**

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۳۸۴۸۱-۷-۶۹۴۱

Approval date

2016-08-10, 1395/05/20

Ethics committee reference number

IR.ARAKMU.REC.1395.148

Health conditions studied1**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 outcomes1**Description**

Urine protein

Timepoint

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

Method of measurement

24h urine protein /mg/dl

Secondary outcomes1**Description**

Hypoglycemia

Timepoint

3 month

Method of measurement

FBS check

Intervention groups1**Description**

Sitagliptin 25mg daily oral for 3 month

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Amiralmomenin Hospital

Full name of responsible person

Dr.Mohammad Ali Ahmadloo

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

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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

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

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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