Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of Effect of pioglitazone on decreasing of proteinuria in type II diabetic patients and kidney disease.

Protocol summary

Summary

The aim of this study is to determine the effect of pioglitazone on proteinuria in patients with type 2 diabetes and nephropathy. This study is a clinical trial of phase 3, two-blind, single-centered. 60 patients with inclusion criteria: 24-hour urine protein over 250 mg / day or albumin to creatinine ratio greater than 30 mg / g. Exclusion criteria: lack of hypothyroidism and heart failure; HbA1C is less than 8; Blood pressure less than 160/100; Creatinine less than 2; GFR is selected from more than 50 randomly. Patients are divided into two groups of 30. In the first group, pioglitazone is given 30 mg daily for two months and in the control group. Checklists are checked after intervention. 24-hour urine protein and albumin and creatinine respond to treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080210222N10**
Registration date: **2017-08-17, 1396/05/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-08-17, 1396/05/26

Registrant information

Name
Zahra Keivani
Name of organization / entity
Shahrekord University Of Medical Sciences
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Iran (Islamic Republic of)
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+98 38 1222 0016
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keivani@skums.ac.ir

Recruitment status

Recruitment complete

Funding source
Shahrekord University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Effect of pioglitazone on decreasing of proteinuria in type II diabetic patients and kidney disease.

Public title

Evaluation of Effect of pioglitazone on decreasing of proteinuria in type II diabetic patients with nephropathy.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclution Criteria: 24-hour urine protein over 250 mg / day or the ratio of albumin to creatinine over 30 mg/g
Exclusion Criteria: Hypothyroidism and heart failure; HbA1C is less than 8; Blood pressure less than 160/100; Creatinine less than 2; GFR greater than 50

Age

No age limit

Gender

Both

Phase

3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences
Street address
shahrekord university of medical sciences, Kashani street, shahrekord
City
Shahrekord
Postal code
IR.SKUMS.REC.1395.39
Approval date
2016-06-19, 1395/03/30
Ethics committee reference number
IR.SKUMS.REC.1395.39

Health conditions studied

1

Description of health condition studied
Diabetic Nephropathy
ICD-10 code
Insulin-de
ICD-10 code description
E10.2

Primary outcomes

1

Description
24-hour urine protein
Timepoint
2 month after intervention
Method of measurement
sampling

Secondary outcomes

1

Description
Albumin level
Timepoint
2month after intervention
Method of measurement
sampling

2

Description
creatinin level
Timepoint
2month after intervention
Method of measurement
sampling

Intervention groups

1

Description
In the first group receive tablet 30 mg pioglitazone daily orally
Category
Treatment - Drugs

2

Description
In the second group receive placebo daily orally
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hajar Hospital in Shahrekord
Full name of responsible person
Ali Momeny
Street address
Parastar street,Hajar Hospital of Shahrekord University of Medical Sciences, shahrekord
City
shahrekord

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Shahrekord University of Medical Science
Full name of responsible person
Dr. Kamal Solati

Street address
Kashani street, shahrekord university of medical sciences, shahrekord
City
Shahrekord
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Shahrekord University of Medical Science
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
Shahrekord University of Medical Sciences
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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