

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 38 1222 0016

###### Email address

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

Inclusion 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

**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

**Full name of responsible person**

Ali Momeny

**Position**

Nephrologist , Professor

**Other areas of specialty/work****Street address**

Parastar street, Kashani Hospital of Shahrekord University of Medical Sciences, shahrekord

**City**

Shahrekord

**Postal code****Phone**

+98 38 3222 0016

**Fax****Email**

Ali.momeny.dr@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahrekord University of Medical Sciences

**Full name of responsible person**

Ali Momeny

**Position**

Nephrologist, professor

**Other areas of specialty/work****Street address**

Parastar street, Kashani Hospital of Shahrekord University of Medical Sciences, shahrekord

**City**

Shahrekord

**Postal code****Phone**

+98 38 3222 0016

**Fax****Email**

Ali.momeny.dr@gmail.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Shahrekord University of Medical

**Full name of responsible person**

Ali Momeny

**Position**

Nephrologist, professor

**Other areas of specialty/work****Street address**

Parastar street, Kashani Hospital of Shahrekord University of Medical Sciences, shahrekord

**City**

Shahrekord

**Postal code****Phone**

00

**Fax****Email**

Ali.momeny.dr@gmail.com

**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*