

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Effect of Pioglitazone on proteinuria, inflammatory and oxidative markers in patient with diabetic nephropathy

#### Protocol summary

##### Summary

60 patients with diabetes type 2 and Glycated hemoglobin (HbA1c) equal or greater than 8 and smaller or equal to 10 and with Glomerular filtration rate (GFR) equal or greater than 30 and smaller or equal to 60 will be selected and randomly will be divided to two groups. For both groups we will start glibenclamide, but only the case group will receive pioglitazone. Both control and case groups were similar in their age; sex; degree of renal function; glycemic control and all the measurable values. The only difference between them was receiving pioglitazone in the case and not receiving it in the control group. After 3 months proteinuria and inflammation (C-Reactive Protein and Ferritin) and oxidative markers (Malondialdehyde and Total Anti-Oxidant) were measured and compared with each other.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013102115105N1**

Registration date: **2014-03-12, 1392/12/21**

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

Last update:

Update count: **0**

##### Registration date

2014-03-12, 1392/12/21

##### Registrant information

###### Name

Farahnoosh Farnood

###### Name of organization / entity

Tabriz University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 914 307 9418

###### Email address

naghavim@tbzmed.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

###### Expected recruitment start date

2014-02-20, 1392/12/01

###### Expected recruitment end date

2014-04-21, 1393/02/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Effect of Pioglitazone on proteinuria, inflammatory and oxidative markers in patient with diabetic nephropathy

###### Public title

Effect of a lowering blood glucose drug on protein loss with urine in patient with kidney disease due to diabetes

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: (The patient with Diabetic nephropathy with Diabetes type 2; Glomerular filtration rate equal or greater than 30; Age greater than 18 & smaller than 65 years old; Agreement to participate in the study) Exclusion criteria: (Glomerular Filtration Rate smaller than 30; Dyspnea; CHF; Liver failure; General edema; Age smaller than 18 & greater than 65 years old; Body Mass Index equal or greater than 40)

###### Age

From **18 years** old to **65 years** old

###### Gender

Both

24 urin and according to miligram per deciliter

## Phase

3

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

##### Street address

Tabriz University of Medical Sciences, Daneshgah Sq.

##### City

Tabriz

##### Postal code

#### Approval date

2014-02-09, 1392/11/20

#### Ethics committee reference number

92183

## Health conditions studied

### 1

#### Description of health condition studied

Diabetic nephropathy

#### ICD-10 code

E10-E14 :

#### ICD-10 code description

Diabetes mellitus With renal complications

## Primary outcomes

### 1

#### Description

Proteinuria

#### Timepoint

Monthly

#### Method of measurement

## Secondary outcomes

### 1

#### Description

Ferritin

#### Timepoint

Monthly

#### Method of measurement

Elisa and according to Nanogram per mililiter

### 2

#### Description

High sensitivity C- Reactive protein

#### Timepoint

Monthly

#### Method of measurement

Elisa according to Nanogram per mililiter

### 3

#### Description

Malondialdehyde

#### Timepoint

Monthly

#### Method of measurement

Elisa and according to micromol per liter

### 4

#### Description

Total antioxidant

#### Timepoint

Monthly

#### Method of measurement

Elisa and according to microgram per mililiter

## Intervention groups

### 1

#### Description

Tablet Pioglitazone, 30 miligram, pathway ocal, daily

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tabriz University of Medical Sciences

##### Full name of responsible person

Farahnoosh Farnood

##### Street address

Nephrology ward, Emam Reza Hospital, Golgasht Ave.

##### City

Tabriz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Tabriz University of Medical Sciences

**Full name of responsible person**

AliReza Ostad Rahimi

**Street address**

Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah Avenue, Daneshgah Square

**City**

Tabriz

**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, Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Farahnoosh Farnood

**Position**

Internist/ Student of Nephrology

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

Nephrology ward, Emam Reza Hospital, Golgasht Ave.

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*