

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Effect of pentoxifyllin on microalbuminuria in patients with diabetic nephropathy

#### Protocol summary

##### Summary

Pentoxifyllin is a phosphodiesterase inhibitor that can decrease proteinuria in patients. The purpose of this study is evaluation of effect of pentoxifyllin on microalbuminuria in diabetic patients. We select 40 diabetic patients that their estimated glomerular filtration rate is higher than 60 mL/min, spot urine albumin-creatinine ratio lesser than 300 mg/g, blood pressure less than 140/90 mmHg by using anti-hypertensive drugs and glycosylated hemoglobin less than 8%. If they have myocardial infarction, stroke, retinal hemorrhage in previous 6 months, immunosuppression drug useage, nonsteroidal anti-inflammatory drugs useage or changing in antihypertensive drugs, are excluded from study. The patients are categorized in two groups and receive pentoxifyllin tablet, 400mg, manufactured by Amin Pharmaceutical, IRAN, 3 times a day for 6 months ,or placebo group as the same . Serum creatinine and spot urine albumin-creatinine ratio are measured at the beginning, three and six months later and compared between groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201312212417N15**

Registration date: **2014-02-23, 1392/12/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-02-23, 1392/12/04

##### Registrant information

###### Name

Firouzeh Moeinzadeh

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1625 5555

##### Email address

moinzade@resident.mui.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

##### Expected recruitment start date

2011-09-23, 1390/07/01

##### Expected recruitment end date

2013-06-21, 1392/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of pentoxifyllin on microalbuminuria in patients with diabetic nephropathy

##### Public title

Effect of pentoxifyllin on microalbuminuria in patients with diabetic nephropathy

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1.Estimated glomerular filtration rate: higher than 60 mL/min/1.73 m<sup>2</sup>; 2.Blood pressure: less than 140/90 mmHg by using anti hypertensive drugs in the last six month 3.protein intake: less than 0.8gr/kg/d; 4.controlled blood glucose (glycosylated hemoglobin:

less than 8%); 5.Spot urine albumin to creatinine ratio: less than 300 mg/g in 3 consecutive measurements during a 3 months screening period. exclusion criteria: 1.Myocardial infarction; 2.Stroke; 3.Retinal hemorrhage in last 6 months; 4.abnormal liver function tests ; 5.Congestive heart failure (New York Heart Association class III or IV); 6.Obstructive uropathy 7.Active malignancy; 8.Patients who could not discontinue immunosuppressive or nonsteroidal anti inflammatory drugs; 9.Pregnant or breast feeding women 10. changes in anti-hypertensive drugs 11.other cause of proteinuria

#### **Age**

From **18 years** old to **90 years** old

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **40**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Vice Chancellor for Research, Isfahan University of Medical Sciences

###### **Street address**

Hezar Jarib Street

###### **City**

isfahan

###### **Postal code**

##### **Approval date**

2011-09-29, 1390/07/07

##### **Ethics committee reference number**

290183

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Diabetic nephropathy

#### **ICD-10 code**

N08.3

#### **ICD-10 code description**

Diabetic nephropathy

### **Primary outcomes**

#### **1**

##### **Description**

Albumin/creatinine ratio of random urine sample

##### **Timepoint**

At beginning, three and six months later

##### **Method of measurement**

Photometric method (mg/g)

#### **2**

##### **Description**

Glomerular filtration rate

##### **Timepoint**

At beginning and the end of study

##### **Method of measurement**

Modification of Diet in Renal Disease (MDRD formula)

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Placebo tablet: three times a day for 6 months manufactured by amin company

##### **Category**

Placebo

#### **2**

##### **Description**

Pentoxifyllin tablet: 400 mg three times a day for 6 month manufactured by amin company

##### **Category**

Treatment - Drugs

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Isfahan endocrine and metabolism research center

###### **Full name of responsible person**

Dr marzieh hoseinbalam

###### **Street address**

khorrām street

###### **City**

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice Chancellor for Research, Isfahan University of Medical Sciences

**Full name of responsible person**

Dr. Peyman Adibi

**Street address**

Hezar Jarib Street

**City**

Isfahan

**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, Isfahan 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**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr.marzieh hoseinbalam

**Position**

Internal medicine resident

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

Sofe street, Alzahra hospital

**City**

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## Person responsible for scientific

## inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Proff of Nephrology

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## Person responsible for updating data

**Contact****Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr. marziyeh hoseinbalam

**Position**

Internal medicine resident

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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*