

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

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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 m²; 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

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Hezar Jarib Street

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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

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

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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