

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### A survey of additive antiproteinuric effect of pentoxifylline on diabetic nephropathy patients with proteinuria taking losartan and enalapril.

#### Protocol summary

##### Summary

In this study the effect of pentoxifylline on protein excretion rate in type 2 diabetic patients taking losartan and enalapril will be evaluated. 100 type 2 diabetic patients with proteinuria, despite taking maximum tolerable dose of above mentioned drugs, will be enrolled. Patients will enter into two groups (losartan+enalapril and losartan+enalapril+pentoxifylline) randomly. The dose of pentoxifylline is 400mg and fixed. Pentoxifylline group patients should not have history or physical signs of intracranial hemorrhage, acute MI and retinal hemorrhage and their urine culture should be negative. The protein excretion rate and HbA1C will be measured in both groups in 3th and 6th month. Blood pressure, creatinine, urea, GFR, and serum potassium are going to be checked monthly. Finally, proteinuria changes will be evaluated in both groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138901013596N1**

Registration date: **2010-05-20, 1389/02/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-05-20, 1389/02/30

##### Registrant information

###### Name

Elena Lak

###### Name of organization / entity

Ahvaz Jundishapur University of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

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###### Recruitment status

**Recruitment complete**

###### Funding source

Ahvaz Jundishapur University of medical sciences

###### Expected recruitment start date

2009-08-23, 1388/06/01

###### Expected recruitment end date

2010-03-21, 1389/01/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

A survey of additive antiproteinuric effect of pentoxifylline on diabetic nephropathy patients with proteinuria taking losartan and enalapril.

###### Public title

Effect of pentoxifylline on urinary protein excretion reduction in diabetic nephropathy patients.

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

inclusion: diabetic nephropathy with GFR more than 30 ml/min and proteinuria more than 150 mg/24h.

exclusion: pentoxifylline sensitivity, congestion heart failure, uncontrolled HTN, patients that received new drug with antiprotein effect (non dihydropyridine calcium channel blockers, spironolactone, beta blockers, diuretics) during study.

###### Age

From **25 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

No information

## Sample size

Target sample size: **100**

## 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,Ahvaz Jundishapur University .

##### Street address

Ahvaz Jundishapur University of medical sciences .

##### City

Ahvaz

##### Postal code

#### Approval date

empty

#### Ethics committee reference number

43//8/20/پ

## Health conditions studied

### 1

#### Description of health condition studied

Non-insulin-dependent diabetes mellitust

#### ICD-10 code

E11

#### ICD-10 code description

Non-insulin-dependent diabetes mellitus

### 2

#### Description of health condition studied

Diabetic Nephropathy

#### ICD-10 code

N08.3

#### ICD-10 code description

Glomerular disorders in diabetes mellitus

## Primary outcomes

### 1

#### Description

Proteinuria in diabets patients

#### Timepoint

3 & 6 month later

#### Method of measurement

measure of protein in 24h urin collection by using colorimetry

## Secondary outcomes

### 1

#### Description

pentoxifylline complications

#### Timepoint

monthly

#### Method of measurement

checklist & phisical exam

### 2

#### Description

measure of GFR

#### Timepoint

monthly

#### Method of measurement

Cockcroft- Gault

### 3

#### Description

measure of serum potasium

#### Timepoint

monthly

#### Method of measurement

flame photometry

## Intervention groups

### 1

#### Description

intervention:400 mg pentoxifyllin daily + enalapril + losartan.

#### Category

Treatment - Drugs

### 2

#### Description

Control:enalapril+losartan

#### Category

Treatment - Drugs

## Recruitment centers

1

**Recruitment center**

**Name of recruitment center**

Naft hospital

**Full name of responsible person**

**Street address**

**City**

Ahvaz

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

research deputy of Ahvaz Jundishapur University

**Full name of responsible person**

Dr Ali Ghorbani

**Street address**

Jundishapur university of Ahvaz-research deputy

**City**

Ahvaz

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

research deputy of Ahvaz Jundishapur University

**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**

Ahvaz Jundishapur University

**Full name of responsible person**

Dr. Elena Lak

**Position**

Internal medicine resident

**Other areas of specialty/work**

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**Email**

elenalak@ajums.ac.ir

**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*