Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 evaluted.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 ,cretinine ,urea , GFR ,and serum potasium are going to be checked monthly.Finally, proteinuria changes will be evaluted 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

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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 sensivity, congestion heart failur, uncontroled HTN, patients that recived new drug with antiprotein effect(non dihydropridine calcium channel blockers, sprinolacton,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:4oo 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

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Email
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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