Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Pentoxifylline on Proteinuria in Patients with Membranous Nephropathy

Protocol summary

Summary
In this randomized, placebo-controlled study, we aim to investigate whether combination of PTX with standard treatment regimen results in additive reduction in proteinuria in patients with membranous nephropathy. Patients with biopsy proven membranous nephropathy are randomized into two groups. Group A receives standard treatment regimen plus pentoxifylline (1200 mg/day), whereas group B receives standard treatment regimen plus placebo. The treatment duration is 6 months for both subgroups. Glomerular filtration rates (GFR) calculated by Cockcroft-Gault formula and urine protein excretion by 24-hour urinary protein will be determined are measured at the baseline and two and six months after intervention.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT138810273043N1**
Registration date: **2010-09-10, 1389/06/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2010-09-10, 1389/06/19

Registrant information
Name
Simin Dashti-Khavidaki
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 6695 4709
Email address
dashtis@sina.tums.ac.ir

Recruitment status
Recruitment complete
Funding source
Tehran University of Medical Sciencies

Expected recruitment start date
2010-01-01, 1388/10/11
Expected recruitment end date
2013-01-01, 1391/10/12
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Pentoxifylline on Proteinuria in Patients with Membranous Nephropathy

Public title
Effect of Pentoxifylline on Proteinuria
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: New cases with biopsy proven Membranous Nephropathy, Initial Random urine protein (mg/dl) > 2 g/day based on 24-hr urine collection Exclusion Criteria: Pregnancy, Breast feeding, Diabetes Mellitus, History of allergy to Pentoxifylline or any derivatives of methyl xanthenes, Cerebral hemorrhage or Retinal hemorrhage within the past 6 months prior to signing the informed consent form, Congestive heart failure (NYHA functional class III or IV), Uncontrolled hypertension (SBP > 200 mmHg and/or DBP > 110 mmHg), history of unstable angina, myocardial infarction, cerebrovascular accidents, Stroke, Obstructive uropathy, Cirrhosis, Hepatic dysfunction as defined by the following laboratory parameters: ALT or AST > 5

times the upper limit of the normal range, or > 3 times concomitant with signs and symptoms of hepatic failure

Age
From **14 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Efficacy study

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice-chancellor for Research

Street address
Tehran University of Medical Sciences

City
Tehran

Postal code

Approval date
2010-05-23, 1389/03/02

Ethics committee reference number
89-01-33-9694

Health conditions studied

1

Description of health condition studied
Membranous Nephropathy

ICD-10 code
N00, N01,

ICD-10 code description
Glomerular Diseases

Primary outcomes

1

Description
urinary protein excretion

Timepoint
2 and 6 months after study initiation

Method of measurement
Measurement of Urinary Protein Excretion based on 24-hr urine collection

Secondary outcomes

1

Description
Glomerular Filtration Rate (GFR)

Timepoint
2 and 6 months after study initiation

Method of measurement
GFR will be calculated by Cockcroft-Gault formula

Intervention groups

1

Description
standard treatment regimen + placebo (400 mg, three times/day, for 6 months)

Category
Placebo

2

Description
standard treatment regimen + pentoxifylline (400 mg, three times/day, for 6 months)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini hospital

Full name of responsible person
Dr. Simin Dashti Khavidaki

Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciencies

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person

Simin Dashti Khavidaki

Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciencies

City

Tehran

Grant name

-

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Simin Dashti Khavidaki

Position

Associate Professor

Other areas of specialty/work

Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences

City

Tehran

Postal code

Phone

+98 21 6695 4709

Fax

Email

dashtis@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shirinsadat Badri

Position

Resident of Clinical Pharmacy

Other areas of specialty/work

Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences

City

Tehran

Postal code

Phone

+98 21 6695 4709

Fax

Email

sh.s.badri@gmail.com

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