

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 Sciences

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 Sciences

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 Sciences

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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

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Shirinsadat Badri

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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