

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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 and 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

**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*