

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Comparison of effect of Tacrolimus and cyclosporine in patients with Idiopathic membranous nephropathy

#### Protocol summary

##### Summary

In this study, patients with Idiopathic membranous nephropathy who refer to special clinic of Kermanshah University of Medical Sciences will investigate. These patients will divide into two equal groups randomly that will match for age and sex. Patients of each group will treat with Cyclosporine or Tacrolimus. After 3 and 6 month of treatment, results of laboratory tests including 24 hours urine protein, urea, creatinine, uric acid, triglyceride and fasting blood sugar will compare between two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014101912685N3**  
Registration date: **2014-11-26, 1393/09/05**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-11-26, 1393/09/05

##### Registrant information

##### Name

Hamidreza Omrani

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3427 6302

##### Email address

hamidomrani@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kermanshah University of Medical Sciences

##### Expected recruitment start date

2014-10-23, 1393/08/01

##### Expected recruitment end date

2015-03-19, 1393/12/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of effect of Tacrolimus and cyclosporine in patients with Idiopathic membranous nephropathy

##### Public title

Comparison of effect of Tacrolimus and cyclosporine in patients with autoimmune nephropathy

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Idiopathic membranous nephropathy had been confirmed by kidney biopsy; Patients have proteinuria more than 3000 mg per day. Exclusion criteria: Patients with secondary Idiopathic membranous nephropathy; Patients with sensitivity to Tacrolimus.

##### Age

From **15 years** old to **70 years** old

##### Gender

Both

##### Phase

2-3

##### Groups that have been masked

*No information*

##### Sample size

Target sample size: **62**

##### Randomization (investigator's opinion)

Randomized

## Randomization description

### Blinding (investigator's opinion)

Single 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 of Kermanshah University of Medical Sciences

##### Street address

Vice Chancellery of Research & Technology, Kermanshah University of Medical Sciences

##### City

Kermanshah

##### Postal code

#### Approval date

2014-07-07, 1393/04/16

#### Ethics committee reference number

9838

## Health conditions studied

### 1

#### Description of health condition studied

Idiopathic membranous nephropathy

#### ICD-10 code

N03

#### ICD-10 code description

Chronic nephritic syndrome

## Primary outcomes

### 1

#### Description

Urine protein

#### Timepoint

Before intervention, after 3 month of intervention and after 6 month of intervention

#### Method of measurement

Urine biochemistry test

### 2

#### Description

Kidney biopsy

#### Timepoint

Before intervention

## Method of measurement

Kidney biopsy test

### 3

#### Description

Blood urea

#### Timepoint

Before intervention, after 3 month of intervention and after 6 month of intervention

#### Method of measurement

Blood biochemistry test

### 4

#### Description

Blood creatinin

#### Timepoint

Before intervention, after 3 month of intervention and after 6 month of intervention

#### Method of measurement

Blood biochemistry test

## Secondary outcomes

### 1

#### Description

Fasting blood sugar

#### Timepoint

Before intervention, after 3 month of intervention and after 6 month of intervention

#### Method of measurement

Blood biochemistry test

### 2

#### Description

Blood triglyceride

#### Timepoint

Before intervention, after 3 month of intervention and after 6 month of intervention

#### Method of measurement

Blood biochemistry test

### 3

#### Description

Blood cholesterol

#### Timepoint

Before intervention, after 3 month of intervention and after 6 month of intervention

#### Method of measurement

Blood biochemistry test

## Intervention groups

### 1

#### Description

Intervention group: Tacrolimus for 6 month with dose of 0.5 mg/kg/day

**Category**

Treatment - Drugs

2**Description**

Control group: Cyclosporine for 6 month with dose of 6 mg/kg/day

**Category**

Treatment - Drugs

**Recruitment centers**1**Recruitment center****Name of recruitment center**

Special clinic of Kermanshah University of Medical Sciences

**Full name of responsible person**

Hamid Reza Omrani

**Street address****City**

Kermanshah

**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Farid Najafi

**Street address**Vice Chancellery of Research & Technology,  
Kermanshah University of Medical Sciences**City**

Kermanshah

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kermanshah 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****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Hamid Reza Omrani

**Position**

Specialist in nephrology

**Other areas of specialty/work****Street address**

Imam Reza hospital

**City**

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**Postal code****Phone**

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**Fax****Email**

hamidomrani@kums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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hamidomrani@kums.ac.ir

**Web page address****Person responsible for updating data****Contact****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*