

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 threat 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 centers1**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 sources1**Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street addressVice 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

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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