Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Iran (Islamic Republic of)
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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
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Specialist in nephrology
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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