

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of mycophenolate mofetil and prednisolone effect as initial treatment on idiopathic membranous nephropathy

Protocol summary

Study aim

Evaluation of Mycophenolate Mofetil and Prednisolone Effect as Initial Treatment on Idiopathic Membranous Nephropathy

Design

In randomized single blinded phase 3 clinical trial study 30 patient divided in two groups. Sampling was done by randomized block sampling and the subjects were randomly assigned to each of the groups. 17 patient received Mycophenolate mofetil and 13 patient received cyclophosphamide for 6 months.

Settings and conduct

This study was conducted on 30 patients in Ahvaz Golestan hospital as blind study and the person who evaluated patient didn't know the kind of drug

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with nephrotic syndrome with more than 4 gr / d of proteins in 24-hour urine or changes in GFR (increase more than 30% without a known cause) and change in serum creatinine, patients with severe and disabling symptoms associated with nephrotic syndrome. Exclusion criteria: Patients with systemic disease, malignancy, active infection, infertility, unstable angina pectoris, type I and type II diabetes, clinical evidence of renal vein thrombosis, acute gastric ulcer or gastrointestinal disease that disturbs the absorption of oral medications.

Intervention groups

Mycophenolate mofetil group, Prednisolone group

Main outcome variables

Urine protein, Albumin, Blood cholesterol and Blood creatinin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180128038539N1**

Registration date: **2018-03-09, 1396/12/18**

Registration timing: **retrospective**

Last update: **2018-03-09, 1396/12/18**

Update count: **0**

Registration date

2018-03-09, 1396/12/18

Registrant information

Name

Shahla Ahmadi halili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3392 3500

Email address

ahmadihalili@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-07-16, 1393/04/25

Expected recruitment end date

2018-01-17, 1396/10/27

Actual recruitment start date

2014-07-16, 1393/04/25

Actual recruitment end date

2018-01-17, 1396/10/27

Trial completion date

empty

Scientific title

Evaluation of mycophenolate mofetil and prednisolone effect as initial treatment on idiopathic membranous nephropathy

Public title

Evaluation of mycophenolate mofetil and prednisolone

effect as initial treatment on idiopathic membranous nephropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with nephrotic syndrome with more than 4 gr / d of proteins in 24-hour urine changes in GFR by increase more than 30% without a known cause in serum creatinine level patients with severe and disabling symptoms associated with nephrotic syndrome

Exclusion criteria:

systemic disease malignancy active infection pregnancy unstable angina pectoris type I and type II diabetes clinical evidence of renal vein thrombosis acute gastric ulcer or gastrointestinal disease that disturbs the absorption of oral medications

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly divided into two groups by randomized blocks

Blinding (investigator's opinion)

Single blinded

Blinding description

Single blind. the person who evaluated patient don't know the kind of drug

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Boulevard, Ahvaz, Iran Ahvaz Khuzestan

Iran, Islamic Republic Of

City

Ahvaz

Province

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Postal code

61357-15794

Approval date

2014-10-11, 1393/07/19

Ethics committee reference number

ajums.REC.1393.226

Health conditions studied

1

Description of health condition studied

Chronic nephritic syndrome

ICD-10 code

N03

ICD-10 code description

Chronic nephritic syndrome

Primary outcomes

1

Description

Urine protein

Timepoint

Before intervention and after 2, 4 and 6 month of intervention

Method of measurement

Urine biochemistry test

2

Description

Albumin

Timepoint

Before intervention and after 2, 4 and 6 month of intervention

Method of measurement

Urine biochemistry test

3

Description

Blood cholesterol

Timepoint

Before intervention and after 2, 4 and 6 month of intervention

Method of measurement

Blood biochemistry test

4

Description

Blood creatinin

Timepoint

Before intervention and after 2, 4 and 6 month of intervention

Method of measurement

Blood biochemistry test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Mycophenolate mofetil with a dose of 1 g every 12 hours for 6 months and prednisolone 0.5 mg/kg/d for 3 months

Category

Treatment - Drugs

2**Description**

Control group: Oral cyclophosphamide with a dose of 1.5 mg/kg/d for 6 months and prednisolone 0.5 mg/kg/d for 6 months

Category

Treatment - Drugs

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

Ahvaz Golestan Hospital

Full name of responsible person

Dr Shahla Ahmadi Halili

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Ahvaz Golestan Hospital, Golestan Boulevard, Ahvaz, Iran

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

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Mohammad Badavi

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Vice Chancellor for Research, Ahvaz Jundishapur University of Medical Sciences, Golestan Boulevard,

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

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Shahla Ahmadi Halili

Position

Physician

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries**Contact**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

all documets

When the data will become available and for how long

unlimited

To whom data/document is available

all readers

Under which criteria data/document could be used

without any criteria

From where data/document is obtainable

Vice Chancellor for Research of Ahvaz Jundishapur
University of Medical Sciences

What processes are involved for a request to access data/document

it is belong to Vice Chancellor for Research of Ahvaz
Jundishapur University of Medical Sciences

Comments