Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Nephropath

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

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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
Street address
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
Street address
Vice Chancellor for Research, Ahvaz Jundishapur University of Medical Sciences, Golestan Boulevard, Ahvaz, Iran
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Email
src@ajums.ac.ir
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 updating data

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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