Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of efficacy and safety of intravenous cyclophosphamide and steroids with oral cyclophosphamide and steroids in the treatment of idiopathic membranous nephropathy

Protocol summary

Study aim

Aim of the study is to assess the efficacy of intravenous cyclophosphamide as compared to oral cyclophosphamide in the treatment of primary membranous nephropathy. Secondary objective is to document side effects of both regimens

Design

Two arm parallel unblinded, Randomized control trial. Sample size is 58. 29 patient in each group. Randomization will be done by lottery method. It will be a singe center study.

Settings and conduct

Indoor and out patient department of Nephrology department of Jinnah hospital. It will be non blinded study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Serum Anti-Phospho Lipase A2 Receptor positive or IgG4 positivity on Immunofluorescence. 2. Biopsy–proven Idiopathic Membranous Nephropathy high risk group (Spot Urine protein/ spot urine creatinine Ratio more than 8g/g). 3. Biopsy –proven Idiopathic Membranous Nephropathy, moderate risk group that has failed to respond to conservative therapy for 6 months. Exclusion Criteria: 1. Patients with clinical, histologic, or serologic evidence of secondary Membranous Nephropathy. 2. Active or ongoing infection/ Recent infection. 3. Allergy or contraindication to cyclophosphamide.

Intervention groups

Patients will be assigned into two groups randomly. Non probability / consecutive sampling technique will be used. One group will be given intravenous cyclophosphamide, 500mg/m2 on 2, 4 and 6 months and steroid on 1, 3 and 5 month as per modified ponticelli regimen. Control group will be given oral cyclophosphamide 2 mg/kg/day on 2, 4 and 6 months and steroids on 1,3 and 5 months as per modified ponticelli regimen.

Main outcome variables

Spot urinary protein: creatinine ratio. Serum creatinine. Side effects like anemia, thrombocytopenia, leucopenia, any infection or hospitalization and malignancy.

General information

Reason for update

Acronym

CIMNT (Cyclophosphamide in membranous nephropathy trial)

IRCT registration information

IRCT registration number: **IRCT20230517058211N1**
Registration date: **2023-07-18, 1402/04/27**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-18, 1402/04/27**
Update count: **0**

Registration date

2023-07-18, 1402/04/27

Registrant information

Name

Fazle Mateen

Name of organization / entity

Allama Iqbal medical college/ Jinnah hospital Lahore

Country

Pakistan

Phone

+92 321 4027280

Email address

fazal.mateen@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-01, 1402/03/11

Expected recruitment end date

2024-05-30, 1403/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and safety of intravenous cyclophosphamide and steroids with oral cyclophosphamide and steroids in the treatment of idiopathic membranous nephropathy

Public title

Intravenous and oral cyclophosphamide in membranous nephropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Serum Anti-Phospho Lipase A2 Receptor positive or IgG4 positivity on Immunofluorescence. Biopsy –proven Idiopathic Membranous Nephropathy, moderate risk group (Spot Urine protein/ spot urine creatinine Ratio between 4 to 8 g/g) that has failed to respond to conservative therapy for 6 months. Biopsy–proven Idiopathic Membtanous Nephropathy high risk group (Spot Urine protein/ spot urine creatinine Ratio more than 8g/g).

Exclusion criteria:

Patients with clinical, histologic, or serologic evidence of secondary Membranous Nephropathy. Evidence of Hepatitis B/C and Human Immunodeficiency Virus Evidence of malignancy (Prostate Specific Antigen, Mammogram, Chest x-ray.) Active or ongoing infection/ Recent infection. Allergy to cyclophosphamide. Contraindication to steroid/ cyclophosphamide

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be assigned into two groups randomly by lottery method. Lottery method will be. Non probability / consecutive sampling technique will be used. The researcher randomly picks envelops for each with numbers, with each number corresponding to a subject in order to create the sample. To create a sample this way, the researcher must ensure that the numbers are well mixed before selecting the sample population.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical review board, Allama Iqbal Medical College/ Jinnah hospital, Lahore

Street address

Allama Shabir Ahmad usmai Road, Lahore .

City

Lahore

Postal code

544550

Approval date

2023-03-31, 1402/01/11

Ethics committee reference number

ERB141/8/31-03-2023/S1ERB

Health conditions studied

1

Description of health condition studied

Primary Membranous Nephropathy

ICD-10 code

N04.2

ICD-10 code description

Nephrotic syndrome with diffuse membranous glomerulonephritis

Primary outcomes

1

Description

Reduction in proteinuria calculated by spot urine protein: creatinine ratio less than 0.2

Timepoint

Monthly for 6 months after starting treatment, then monthly follow up after 6 months of completion of treatment. Total 12 months

Method of measurement

Spot urine sample will be send to lab

Secondary outcomes

1

Description
Hemoglobin
Timepoint
Monthly for 6 months after starting treatment (duration of treatment 6 months), then monthly follow up after 6 months of completion of treatment. Total 12 months
Method of measurement
Blood sample

2

Description
White cell count
Timepoint
Monthly for 6 months after starting treatment (duration of treatment 6 months), then monthly follow up after 6 months of completion of treatment. Total 12 months
Method of measurement
Blood sample

3

Description
Reduction in Serum Creatinine
Timepoint
Monthly for 6 months after starting treatment (duration of treatment 6 months), then monthly follow up after 6 months of completion of treatment. Total 12 months
Method of measurement
Blood sample

Intervention groups

1

Description
Intervention group: Intravenous cyclophosphamide 500mg/m2 on 2, 4 and 6 months. Injection Cyclophosphamide wil be given as infusion of 100 ml saline over 1 hour. Before infusion patient's cell count and C Reactive protein (CRP) will be checked. In months 1, 3 and 5 Injection Methypredisolone 1gram intravenously once a day for first 3 days, then Tab Prednisolone 0.5 mg/Kg body weight will be given in two divided doses for next 27 days.Total treatment wil be of six months
Category
Treatment - Drugs

2

Description
Control group: Oral cyclophosphamide 2mg/kg in two divided doses on 2,4 and 6 months. Before cyclophosphamide treatment patient's cell count and C Reactive protein (CRP) will be checked. In months 1, 3 and 5 Injection Methypredisolone 1gram intravenously once a day for first 3 days, then Tab Prednisolone 0.5 mg/Kg body weight will be given in two divided doses for next 27 days. Total treatment wil be of six months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Nephrology department, Jinnah Hospital, Lahore
Full name of responsible person
Dr Muhammad Saleem
Street address
Allama Iqbal Medical College,Allama Shabir Ahmad Usmani Road, Lahore
City
Lahore
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54550
Phone
+92 332 8376745
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saleemdr5@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jinnah Hospital/ Allama Iqbal Medical College
Full name of responsible person
Dr Muhammad Saleem
Street address
Jinnah Hospital , Allama Shabir Ahmad Usmani Road, Faisal Town
City
Lahore
Postal code
54550
Phone
+92 332 8376745
Email
saleemdr5@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Jinnah Hospital/ Allama Iqbal Medical College
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
Jinnah Hospital/ Allama Iqbal Medical College

Full name of responsible person
Dr Muhammad Saleem

Position
Consultant Nephrologist

Latest degree
Specialist

Other areas of specialty/work
Nephrology

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Jinnah Hospital , Allama Shabir Ahmad Usmani Road, Faisal Town

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Consultant Nephrologist

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Jinnah Hospital/ Allama Iqbal Medical College

Full name of responsible person
Dr Fazl e Mateen

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Nephrology

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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
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Intravenous versus oral cyclophosphamide in Primary Membranous Nephropathy. Data will be availale in Excel sheets of all participants of study including their primary and secondary outcomes

When the data will become available and for how long
Data about the participants of both arms and their outcomes will be available Data will be available after May 2024 and it will be available 6 months after publication

To whom data/document is available
Only for doctors working in teaching institutes

Under which criteria data/document could be used
Data can only be used by health professionals for research purposes

From where data/document is obtainable
Data will be available through email: saleemdr5@gmail.com

What processes are involved for a request to access data/document
Person who needs data should ask for permission of usage of data through email provided. Email should include name, position held, teaching institute and purpose of using data.

Comments

Our study data will be available for any ongoing study if needed