

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 single 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 Membranous 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 envelopes 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 will 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 Methylprednisolone 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 will 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 Methylprednisolone 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 will 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

Postal code

54550

Phone

+92 332 8376745

Email

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

Street address

Jinnah Hospital , Allama Shabir Ahmad Usmani Road,
Faisal Town

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Lahore

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Phone

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Person responsible for scientific 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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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

Street address

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Postal code

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Phone

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Email

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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 available 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