Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of long-term Maintenance Therapy with Mycophenolate Mofetil in Lupus Nephritis

Protocol summary

Summary

The purpose of this study is to define the outcome of renal function with mycophenolate mofetil (MMF) and steroid according to our protocol. Twenty four patients with the diagnosis of lupus in accordance with ACR classification criteria were enrolled. Inclusion criteria was defined by evidence of active proliferative glomerulonephritis in the renal biopsy (WHO class IV or III lupus nephritis). Exclusion criteria include :WHO class I or II, end stage renal disease, leukopenia, infection, history of cytotoxic drug treatment. Study protocol: Induction: intravenous cyclophosphamide, given as boluses once a month for 3-6 consecutive months in addition to steroid. Maintenance: MMF (up to 2gr/day) combined with steroid. Tapering: MMF dosage remains unchanged for the first year followed by dose reduction in the second year and then discontinuation. Patients were followed up every month during induction therapy and every other month during the first year and every 3 months thereafter. End points: Criteria for: Criteria for complete remission: a) Complete improvement of renal and extra-renal symptoms b) Return to within normal limits of ESR, C3, C4, Hb and fall of autoantibody titers c) Absence of relapses and infectious complications Criteria for partial remission: a) No progression of renal disease b) Regression of systemic symptoms c) Decrease of at least 50% in dysmorphic RBC, cellular casts and proteinuria or less than 1 gr proteinuria per day d) Return to within normal limits of markers of inflammation Criteria for relapse: a) More than 50% increase in serum creatinine, dysmorphic RBC , cellular cast b) Doubling of proteinuria c) At least two systemic symptoms reappeared Criteria for refractory to therapy: No renal response in spite of 6 month treatment Criteria for end stage renal disease: Plasma creatinine rose and got stabilized above 5mg/dl for 3 months

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012071710313N1**
Registration date: **2013-02-04, 1391/11/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-02-04, 1391/11/16

Registrant information

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2007-12-31, 1386/10/10

Expected recruitment end date

2012-12-31, 1391/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Efficacy of long-term Maintenance Therapy with Mycophenolate Mofetil in Lupus Nephritis

Public title
Efficacy of Mycophenolate Mofetil on kidney involvement in Lupus patients

Purpose
Treatment

Inclusion/Exclusion criteria
Twenty four consecutive patients with the diagnosis of lupus in accordance with ACR classification criteria were enrolled. Inclusion criteria: evidence of active proliferative glomerulonephritis in the renal biopsy (WHO class IV, III). In case of absent renal biopsy or the presence of WHO class V in biopsy, following clinical or paraclinical findings: proteinaria >1 gr/24 h (or sustained 2 to 4+ proteinuria); progressive renal failure with 30% decrease in creatinine clearance over one-year period and creatinine > 1.9 mg/dL; the presence of more than 5 red cells in HPF of urine sediment in two separate specimens taken in a year, presence of WBC, granular or hyaline casts without active infection Exclusion criteria: WHO class I or II lupus nephritis; end stage renal disease when replacement renal therapy will be indicated, leukopenia (neutrophils < 1500/mm3) due to bone marrow suppression; recurrent episodes of bacterial infection; history of cytotoxic drug treatment for more than two weeks or pulse therapy with corticosteroids during a six-week period before study entry.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mashhad University of Medical Sciences

Street address
Mashhad University of Medical Sciences, Mashhad-Iran, Tel.:(+98 511) 8412081, Fax:(+98 511)8430249, Email:ramresearch@mums.ac.ir

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Mashhad

Postal code

Approval date
2007-12-31, 1386/10/10

Ethics committee reference number
2106ت

Health conditions studied

1

Description of health condition studied
lupus nephritis

ICD-10 code
M32.1

ICD-10 code description
Systemic lupus erythematosus with organ or system involvement

Primary outcomes

1

Description
Complete remission

Timepoint
Patients were followed up every month during induction therapy and every other month during the first year and every 3 months thereafter during 24 month maintenance therapy.

Method of measurement
a) Complete improvement of renal and extra-renal symptoms b) Return to within normal limits of ESR, C3, C4, Hb and fall of autoantibody titers c) Absence of relapses and infectious complications

Secondary outcomes

1

Description
Partial remission

Timepoint
Patients were followed up every month during induction therapy and every other month during the first year and every 3 months thereafter during 24 month maintenance therapy.

Method of measurement
a) No progression of renal disease b) Regression of systemic symptoms c) Decrease of at least 50% in dysmorphic RBC, cellular casts and proteinuria or less than 1 gr proteinuria per day d) Return to within normal limits of markers of inflammation

Intervention groups

1

Description
The treatment considered as four phases for classes III and IV of lupus nephritis: 1) Induction: intravenous cyclophosphamide, given as boluses once a month for 3-6 consecutive months in addition to corticosteroid. 2) Maintenance: mycophenolate mofetil (to the maximum dose of 2 gr /day) combined with corticosteroid. 3) Tapering: mycophenolate mofetil dosage remaines unchanged for the first year followed by dose reduction in the second year, in the absence of relapse or partial remission fulfilment. 4) Discontinuation : if our study goals had been achieved , the mycophenolate mofetil would have been discontinued with the further tapering of prednisolone to the lowest possible dose every day or every other day and patients' follow-up for evidence of relapse. Those with class V lupus nephritis were given mycophenolate mofetil combined with corticosteroid since the diagnosis was made

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem Hospital

Full name of responsible person
zahra rezaieyazdi

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mashhad- ghaem hospital- rheumatic diseases research center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad university of medical Sciences

Full name of responsible person
Dr.Tafaghodi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad 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

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Associate Professor of Rheumatology

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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