

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

Zahra Rezaieyazdi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1801 2753

Email address

rezaieyazdiz@mums.ac.ir

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: proteinuria >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

City

Mashhad

Postal code**Approval date**

2007-12-31, 1386/10/10

Ethics committee reference number

2106

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 remains 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

Street address

mashhad- ghaem hospital- rheumatic diseases research center

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad university of medical Sciences

Full name of responsible person

Dr.Tafaghodi

Street address

Research vice chancellor, Mashhad University of Medical Sciences, Daneshgah St., Mashhad

City

Mashhad

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

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Rezaieyazdi

Position

Associate Professor of Rheumatology

Other areas of specialty/work

Street address

Rheumatic Diseases Research Center, Ghaem Hospital, Mashhad University of Medical Sciences

City

Mashhad

Postal code

Phone

+98 51 1801 2753

Fax

Email

rezaieyazdiz@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Rezaieyazdi

Position

Associate Professor of Rheumatology

Other areas of specialty/work

Street address

Rheumatic Diseases Research Center, Ghaem Hospital, Mashhad University of Medical Sciences

City

Mashhad

Postal code

Phone

+98 51 1841 0136

Fax

Email

rezaieyazdiz@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Rezaieyazdi

Position

Associated Professor of Rheumatology

Other areas of specialty/work

Street address

Rheumatic Diseases Research Center, Ghaem
Hospital, Mashhad University of Medical Sciences,
Iran

City

Mashhad

Postal code

Phone

+98 51 1841 0136

Fax

+98 51 1841 0138

Email

rezaieyazdi@mums.ac.ir

Web page address

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