

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The effect of mycophenolate mofetil in controlling the recurrence of idiopathic nephrotic syndrome in steroid-dependent children or frequent recurrence in patients referred to pediatric nephrology clinic, Imam Reza hospital

Protocol summary

Study aim

The effect of mycophenolate mofetil in controlling the recurrence of idiopathic nephrotic syndrome in steroid-dependent children or frequent recurrence in patients referred to pediatric nephrology clinic, Imam Reza hospital

Design

This study is a non-blinded clinical trial. The study population will be included all children with steroid-dependent idiopathic nephrotic syndrome or frequent recurrent that referring to pediatric nephrology clinic, Imam Reza hospital of Kermanshah city 2006-2018. 12 eligible patients will be selected conveniently and randomly will be assigned to the intervention and control group.

Settings and conduct

This study which will be conducted in Imam Reza hospital of Kermanshah city is non-blinded one. At the beginning and the end of the study, digestive complications, infection and leukopenia are recorded in a checklist

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ages 1 to 12 years
Exclusion criteria: Patients who have been treated with MMF for at least 6 months

Intervention groups

The intervention group will receive MMF in a dose of 600 mg / m² every 12 hours. Corticosteroid dose of 60mg / m² increases for three consecutive days until negative proteinuria. The control group will not receive intervention

Main outcome variables

Digestive complications; Infection; Leukopenia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N113**

Registration date: **2019-02-24, 1397/12/05**

Registration timing: **prospective**

Last update: **2019-02-24, 1397/12/05**

Update count: **0**

Registration date

2019-02-24, 1397/12/05

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-06, 1397/12/15

Expected recruitment end date

2019-06-05, 1398/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mycophenolate mofetil in controlling the recurrence of idiopathic nephrotic syndrome in steroid-dependent children or frequent recurrence in patients referred to pediatric nephrology clinic, Imam Reza hospital

Public title

The effect of mycophenolate mofetil in controlling the recurrence of idiopathic nephrotic syndrome in steroid-dependent children or frequent recurrence

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ages 1 to 12 years

Exclusion criteria:

Patients who have been treated with MMF for at least 6 months

Age

From **1 year** old to **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly Individually by random number table via code receipt

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

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-09-11, 1397/06/20

Ethics committee reference number

ir.kums.rec.1397.938

Health conditions studied

1

Description of health condition studied

Nephrotic syndrome

ICD-10 code

N04

ICD-10 code description

Nephrotic syndrome

Primary outcomes

1

Description

Digestive complications

Timepoint

The beginning, end of the study and every three months

Method of measurement

Asking the patient

2

Description

Infection

Timepoint

The beginning and end of the study

Method of measurement

Doctor's observation

3

Description

Leukopenia

Timepoint

The beginning and end of the study

Method of measurement

blood test

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive MMF in a dose of 600 mg / m² every 12 hours. Corticosteroid dose of 60mg / m² increases for three consecutive days until negative proteinuria.

Category

Treatment - Devices

2

Description

The control group will not receive intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Parastar Boulevard

Full name of responsible person

Mahdi Rafati

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

mrafati41@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Vice chancellor for research of Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3836 0014

Email

fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Mahdi Rafati

Position

Resident of child

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

mrafati41@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Seyed Abolhasan Seyedzadeh

Position

Faculty Member of Kermanshah University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Emam Reza Hospital, Parastar Boulevard

City

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Province

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Postal code

6715847141

Phone

+98 83 3427 6306

Email

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Mahdi Rafati

Position

Resident of child

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared

When the data will become available and for how long

3 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

What processes are involved for a request to access data/document

In a 15-day period, the documents will be sent e-mail

Comments