

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Study of levamisole effect in reduction of relapse rate in children with frequently relapsing/steroid dependent idiopathic nephrotic syndrome

Protocol summary

Summary

Treatment of frequently relapsing (FR) or steroid dependent (SD) idiopathic nephrotic syndrome remains a great challenge because of prolonged courses of steroid use with potential for serious complications. Some drugs, including cyclophosphamide, cyclosporine, chlorambucil, MMF, have been used as second line drugs to reduce the dose of corticosteroids; but most of them have serious complications. Levamisole, an antihelminthic drug has been used as steroid-sparing agent in idiopathic nephrotic syndrome. Regarding to fewer complications of levamisole in comparison with other steroid-sparing drugs, effectiveness of levamisole in reducing the number of relapses and cumulative dose of steroid in FRNS and SDNS would let to use it as the first line steroid-sparing agent. Our study is a before-after clinical trial in which we evaluate the effectiveness of levamisole in thirty 1-14 year old patients with frequently relapsing or steroid dependent idiopathic nephrotic syndrome. Patients will be treated with prednisolone 40 mg/m²/day in their relapse episode till remission is achieved, then Levamisole 2.5 mg/kg every other day will be administered and the dose of prednisolone will be continued with the dose of 0.5-1 mg/kg every other day. Prednisolone will be tapered gradually until it can be discontinued or the least effective dose for control of relapses is achieved. Level of proteinuria and clinical signs will be evaluated every 1-2 months. Liver function tests and CBC will be assessed every 4 months. Then relapse rate (relapse/year) and cumulative dose of prednisolone (mg/m²/year) will be compared before and after the beginning of levamisole.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106066589N2**

Registration date: **2011-08-15, 1390/05/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-08-15, 1390/05/24

Registrant information

Name

abolhassan seyedzadeh

Name of organization / entity

kemanshah university of medical sciences

Country

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Phone

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor of Research and Technology;
Kermanshah University of Medical Sciences

Expected recruitment start date

2010-09-21, 1389/06/30

Expected recruitment end date

2011-12-22, 1390/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of levamisole effect in reduction of relapse rate in children with frequently relapsing/steroid dependent idiopathic nephrotic syndrome

Public title

Levamisol effect in reducing relapse rate of nephrotic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: idiopathic nephrotic syndrome; frequent relapses or dependency to steroid; age 1-14 years old.

Exclusion criteria: the patients who consume levamisole less than 6 months; need to start other immunosuppressive drugs to control the relapses.

Age

From **1 year** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Research

Street address

Kermanshah University of Medical Sciences

City

Kermanshah

Postal code**Approval date**

2011-01-15, 1389/10/25

Ethics committee reference number

7/420/1800450

Health conditions studied**1****Description of health condition studied**

nephrotic syndrome

ICD-10 code

N04

ICD-10 code description**Primary outcomes****1****Description**

rate of relapses of nephrotic syndrome

Timepoint

during the whole period of study

Method of measurement

in relapses/year

2**Description**

cumulative dose of prednisolone

Timepoint

during the whole period of the study

Method of measurement

in mg/kg body weight/year

Secondary outcomes**1****Description**

neutropenia

Timepoint

every 4 months

Method of measurement

CBC

2**Description**

liver enzymes elevation

Timepoint

every 4 months

Method of measurement

AST,ALT

3**Description**

seizure

Timepoint

during the study period

Method of measurement

clinical

Intervention groups**1****Description**

In patients with relapse of NS, the relapse episode is controlled with prednisolone 40 mg/m²/day for 7-10 days and then levamisole 2.5 mg/m²/every other day is administered while prednisolone is tapered gradually. These two drugs are continued until

prednisolone can be discontinued or the side effects of levamisole happen.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital

Full name of responsible person**Street address****City**

Kermanshah

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Vice-Chancellor of Research and Technology

Street address

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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

Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Abolhassan Seyedzadeh

Position

Associate Professor

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Kermanshah University of Medical Sciences

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Bitia Alimardani

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Pediathric Resident

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Kermanshah

Postal code**Phone****Fax****Email****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