

# 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/m<sup>2</sup>/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/m<sup>2</sup>/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

Iran (Islamic Republic of)

###### Phone

+98 831427630108

###### Email address

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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/m<sup>2</sup>/day for 7-10 days and then levamisole 2.5 mg/m<sup>2</sup>/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**

Kermanshah University of Medical Sciences

**City**

Kermanshah

**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

**Full name of responsible person**

Bitia Alimardani

**Position**

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*