

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Determination of effective therapeutic regimen via Levamisole in controlling the idiopathic nephrotic syndrome relapse among children

Protocol summary

Study aim

Comparison of daily and every-other-day therapeutic regimen with Levamisole in relapse control of idiopathic nephrotic syndrome in children

Design

This study was randomized without control group. 188 children with nephrotic syndrome are randomly divided into two equal groups. In the first group, patients will receive 2.5 mg / kg levamisole daily and the second group will receive the same Levamisole dose every other day.

Settings and conduct

The study is carried out at Imam Reza Hospital in Kermanshah after obtaining written consent from parents with random allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with steroid-dependent idiopathic nephrotic syndrome and history of use of steroid supplementation, Age range 2 to 15 years
Exclusion criteria: The patient was treated with levamisole for at least 4 months (minimum follow-up period) at the initial days of study. The child's affection with any chronic disease except for nephrotic syndrome. Need to replace Levamisole with another medication due to lack of control of relapses as per the opinion of the physician. Early relapse (relapse in the first month of treatment with Levamisole). Inappropriate and timely dosage of medication by the patient. Failure to refer the patient to complete the treatment process and make necessary evaluations during the follow-up period of the study

Intervention groups

Intervention group 1: Levamisole (manufactured by Rooz Daroo Pharmaceutical Co.), daily administration 2.5 mg/kg. Intervention group 2: Levamisole (manufactured by Rooz Daroo Pharmaceutical Co.), every-other-day administration 2.5 mg/kg.

Main outcome variables

Recurrent Nephrotic Syndrome, Corticosteroid Dosage, Medication Side Effects, Levamisole Dosage

Effectiveness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180519039715N3**

Registration date: **2019-12-08, 1398/09/17**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-08, 1398/09/17**

Update count: **0**

Registration date

2019-12-08, 1398/09/17

Registrant information

Name

Sara Hookari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3826 4513

Email address

s.hookari@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of effective therapeutic regimen via Levamisole in controlling the idiopathic nephrotic syndrome relapse among children

Public title

Determination of effective therapeutic regimen via Levamisole in controlling the idiopathic nephrotic syndrome relapse among children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients affliction with steroid-dependent idiopathic nephrotic syndrome or with high number of relapses 2-15 years old non-use of steroid supplementation

Exclusion criteria:

Patient treatment with Levamisole for less than 4 months (the minimum follow-up period) the children's affliction with any chronic disease other than nephrotic syndrome

Age

From **2 years** old to **15 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **188**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization and random assignment of people to two groups is done by generating random numbers using the random number table.

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

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

Medical Sciences Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6719851115

Approval date

2019-09-17, 1398/06/26

Ethics committee reference number

IR.KUMS.REC.1398.687

Health conditions studied

1

Description of health condition studied

Pediatric Nephrotic Syndrome

ICD-10 code

N04

ICD-10 code description

Nephrotic syndrome

Primary outcomes

1

Description

Recurrence of Pediatric Nephrotic Syndrome

Timepoint

4 Weeks

Method of measurement

Three-plus Proteinuria (measured by a special tape that contains protein indicator; three-plus and higher is considered relapse) on three consecutive days at the end of each month.

Secondary outcomes

1

Description

Dose of corticosteroid

Timepoint

4 Weeks

Method of measurement

Laboratory results and clinical evaluation

2

Description

Drug side effects

Timepoint

4 Weeks

Method of measurement

Ask the patient or his legal guardian, as well as laboratory results and clinical evaluations

Intervention groups

1

Description

Intervention group 1: Levamisole (manufactured by Rooz Daroo Pharmaceutical Co.), daily administration 2.5 mg/kg

Category

Treatment - Drugs

2

Description

Intervention group 2 : Levamisole (manufactured by Rooz Daroo Pharmaceutical Company), daily administration 2.5 mg/kg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr. Ali Soroush

Street address

Bagh Abrisham Blvd

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6719851451

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Korosh Hamzehee

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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

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

Ali Shourmij

Position

Medical doctor

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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