Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 levovisol 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
City
Kermanshah
Province
Kermanshah
Postal code
6719851451
Phone
+98 83 3826 4513
Email
Ali.Soroush@Kums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Koroush Hamzehee
Street address
Building of Vice Chancellor for Research Affairs, Building No.2, Shahid Beheshti Blvd
City
Kermanshah
Province
Kermanshah
Postal code
6714697956
Phone
+98 83 3836 0014
Email
khamzehee@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
Ali Shourmij
Position
Medical doctor
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Emam Reza Hospital, Bagh Abrisham Blvd
City
Kermanshah
Province
Kermanshah
Postal code
6719851451
Phone
+98 83 3826 4513
Email
ash_baunv@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Seyed Abolhasan Seyedzadeh
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Emam Reza Hospital, Bagh Abrisham Blvd
City

Kermanshah
Province
Kermanshah
Postal code
6719751451
Phone
+98 83 3826 4513
Fax
Email
asayedzadeh@kums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Sara Hookari
Position
Reasecher
Latest degree
Master
Other areas of specialty/work
Biostatistics
Street address
Emam Reza Hospital, Bagh Abrisham Blvd
City
Kermanshah
Province
Kermanshah
Postal code
6714697956
Phone
+98 83 3835 0121
Email
sara_hoo64@yahoo.com

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