

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the Effect of Montelukast as an adjunctive therapy on Treatment results (Proteinuria, Edema, Albumin Level) of Nephrotic Syndrome in Children

Protocol summary

Study aim

Evaluation the Effect of Montelukast as an adjunctive therapy on Nephrotic Syndrome in Children

Design

This assessment is a clinical trial in Phase 3, children diagnosed with nephrotic syndrome that have been verified by pediatric specialist, are considered as study group. In this study, 40 children who meet the criteria are selected. Patients are categorized based on non randomization method, 20 children in the intervention group and 20 children in the control group. Accordingly, at the beginning of the diagnosis and 1 months after the start of treatment, the condition of the nephrotic syndrome is evaluated by signs and symptoms.

Settings and conduct

This study will be done as a clinical trial at the pediatric Clinic of Amir Kabir Hospital in Arak, Also the study will also be single blinded in which patients will be blinded in study.

Participants/Inclusion and exclusion criteria

Inclusion criteria is the only Nephrotic Syndrome, while patients who are not available during the next year to refer to the facility for follow-up or have other underlying conditions (such as hematology diseases or any other chronic disease), or intake drug for another illness, were excluded.

Intervention groups

In intervention group, in addition to the usual treatment of nephrotic syndrome (corticosteroid), we also used vitamin D, in which Montelukast is administered as tables of 5 mg, in addition in control group we used the usual treatment for Nephrotic Syndrome is 60 mg / m² / day is 60 mg of prednisolone (maximum dose of 80 mg / m² / day) for 4-6 weeks, which is used in the control group.

Main outcome variables

Albumin level, Urinary tract infection, Edema

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130518013366N13**

Registration date: **2020-03-24, 1399/01/05**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-24, 1399/01/05**

Update count: **0**

Registration date

2020-03-24, 1399/01/05

Registrant information

Name

Parsa Yousefi Chaijan

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-08, 1398/06/17

Expected recruitment end date

2020-09-06, 1399/06/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the Effect of Montelukast as an adjunctive therapy on Treatment results (Proteinuria, Edema, Albumin Level) of Nephrotic Syndrome in Children

Public title

The effect of Montecukast on Nephrotic Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Affected to Nephrotic Syndrome

Exclusion criteria:

Underlying blood disease Underlying liver disease

Age

To 15 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

This means that patients in groups do not know the used drugs, and drugs has similar packaging.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Sardasht, Arak

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Postal code

3848176941

Approval date

2019-11-16, 1398/08/25

Ethics committee reference number

IR.ARAKMU.REC.1398.228

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

Albumin level

Timepoint

Before treatment and 2 months after the administration of Montelukast

Method of measurement

Blood test

2

Description

Urinary tract Infection

Timepoint

Before treatment and 2 months after the administration of Montelukast

Method of measurement

Urine test

3

Description

Edema

Timepoint

Before treatment and 2 months after the administration of Montelukast

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In these patients, in addition to the usual treatment of nephrotic syndrome including 60 mg / m2 / day is 60 mg of prednisolone (maximum dose of 80 mg / m2 / day) for 4-6 weeks, we also used Montelukast, in which Montelukast as tables of 5 mg administered daily.

Category

Treatment - Drugs

2**Description**

Control group: The usual treatment for Nephrotic Syndrome is 60 mg / m² / day is 60 mg of prednisolone (maximum dose of 80 mg / m² / day) for 4-6 weeks, which is used in the control group.

Category

Treatment - Drugs

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

Department of Pediatrics, Amir Kabir Hospital

Full name of responsible person

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

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Full name of responsible person

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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

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Fatemeh javidi

Position

Pediatric resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatric

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Associate Professor of Pediatric Nephrology

Latest degree

Subspecialist

Other areas of specialty/work

Pediatric Nephrology

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Position

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Latest degree

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Phone**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