

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigation of the effect of using Montelukast on reducing the recurrence of steroid dependence nephrotic syndrome

Protocol summary

Study aim

Investigation of the effect of using Montelukast on reducing the recurrence of steroid dependence nephrotic syndrome

Design

Clinical trial with control and parallel groups, single blind, simple randomization

Settings and conduct

This study is carried out on children with nephrotic syndrome referring to Dr.Seikh Hospital in Mashhad. Convenience sampling method is used. Patients with nephrotic syndrome who had one-time minor recurrence with 1+ and 2+ Proteinuria, in case of being under 15 years old and acquiring parents' consent for participation, will enter the study. Complications related to Montelukast such as stomachache, gastrointestinal symptoms, mood disorders will be controlled and recorded and cases will be excluded from the study if necessary. Ratio of urine protein to creatinine, Serum Albumin, rate of short term recovery, and complications in all patients will be evaluated before and one month after the beginning of the treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with frequently relapsing nephrotic syndrome and sensitivity to steroid. Exclusion criteria: extreme edema, resistance to treatment with Corticosteroid

Intervention groups

Intervention group: One 5-mg Montelukast pill (produced by Adibi-pharma company) is prescribed daily for one month with 1 mg/kg Prednisolone Control group: Prednisolone (produced by Iran-hormone company) with dosage of 1 mg/kg is prescribed for a month. Maximum daily dosage is 60 mg.

Main outcome variables

ratio of urine protein to creatinine, Serum Albumin, creatinine, Cholesterol, rate of short term recovery, and complications in all patients before and one month after the beginning of the treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111024007892N9**

Registration date: **2020-04-03, 1399/01/15**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-03, 1399/01/15**

Update count: **0**

Registration date

2020-04-03, 1399/01/15

Registrant information

Name

Anoosh Azarfar

Name of organization / entity

Mashhad University of Medical Sciences, Faculty of Nursing and Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 51 1606 1227

Email address

azarfara@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-09, 1398/07/17

Expected recruitment end date

2020-10-11, 1399/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of using Montelukast on reducing the recurrence of steroid dependence nephrotic syndrome

Public title

Use of Montelukast in reducing the recurrence of steroid dependence nephrotic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with frequently relapsing nephrotic syndrome (4 times or more in a year) sensitivity to steroid (proper response to treatment with oral Corticosteroid with dosage of 1-2 mg/kg in a patient)

Exclusion criteria:

extreme edema resistance to treatment with Corticosteroid

Age

To **15 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is performed using table of random numbers produced by www.randomization.com website in such a way that numbers are placed in sealed envelopes and each envelope is allocated to one patient assigning them to one of the two groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The analyst will be unaware of the intervention and control groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2019-06-18, 1398/03/28

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.511

Health conditions studied

1

Description of health condition studied

frequently relapsing nephrotic syndrome with sensitivity to steroid

ICD-10 code

N04.0

ICD-10 code description

Nephrotic syndrome with minor glomerular abnormality

Primary outcomes

1

Description

ratio of urine protein to creatinine

Timepoint

before and one month after the beginning of treatment

Method of measurement

biochemical test

2

Description

Serum Albumin

Timepoint

before and one month after the beginning of treatment

Method of measurement

biochemical test

3

Description

creatinine

Timepoint

before and one month after the beginning of treatment

Method of measurement

biochemical test

4

Description

Cholesterol

Timepoint

before and one month after the beginning of treatment

Method of measurement

investigation in laboratory

5

Description

short term rate of recovery

Timepoint

one month after the beginning of treatment

Method of measurement

clinical observation

6

Description

complications

Timepoint

one month after the beginning of treatment

Method of measurement

clinical observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: One 5-mg Montelukast pill (produced by Abidi-pharma company under Airokast brand name) is prescribed daily for one month with 1 mg/kg Prednisolone

Category

Treatment - Drugs

2

Description

Control group: Prednisolone (produced by Iran-hormone company) with dosage of 1 mg/kg for one month will begin. (maximum dosage of 60 mg per day)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Sheikh Hospital

Full name of responsible person

Sahar Malaekheh

Street address

Dr. Sheikh Hospital, Tohid Square, Taheri Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

63185- 91399

Phone

+98 51 3726 9021

Email

malaekhehns961@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

91778-99191

Phone

+98 51 3841 2081

Email

ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Sahar Malaekheh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Dr. Sheikh Hospital, Tohid Square, Taheri Ave

City

Mashhad

Province

Razavi Khorasan

Postal code
63185- 91399
Phone
+98 51 3726 9021
Email
malaekehns961@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Anoosh Azarfara
Position
Associated professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Dr. Sheikh Hospital, Tohid Square, Taheri Ave
City
Mashhad
Province
Razavi Khorasan
Postal code
63185- 91399
Phone
+98 51 3726 9021
Email
azarfara@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Anoosh Azarfara
Position
Associated professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics

Street address
Dr. Sheikh Hospital, Tohid Square, Taheri Ave
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are published.

To whom data/document is available

Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used

Carrying out analysis on data is permitted.

From where data/document is obtainable

Data can be accessible through sending an email to the corresponding author.

What processes are involved for a request to access data/document

After sending a request email to the corresponding author, data will be sent in 1 month.

Comments