Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of Sequential versus Concurrent Albumin and Furosemide in Pediatric Nephrotic Syndrome Patients

Protocol summary

Study aim
Determining the effectiveness of sequential and simultaneous administration of albumin and furosemide in edema reduction in pediatric nephrotic syndrome

Design
A parallel blinded randomized trial on 128 pediatric patients with Nephrotic Syndrome

Settings and conduct
This study is conducted in a referral teaching pediatric hospital. Hospitalized patients with edema and hypoalbuminemia are treated with therapeutic doses of albumin and furosemide. these patients are allocated by block randomization. The patient, the Research evaluator, and the Analyzer will be blind to the research.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 2 to 15 years old, children diagnosed with nephrotic syndrome

Intervention groups
One group received a mixture of Albumin and Furosemide simultaneously and the other group receives albumin first and then furosemide (after albumin administration).

Main outcome variables
Patient weight and Urine Sodium level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120415009475N11**
Registration date: **2022-02-22, 1400/12/03**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-22, 1400/12/03**
Update count: **0**

Registration date
2022-02-22, 1400/12/03

Registrant information

Name
Bahador Mirrahimi
Name of organization / entity
Shahid Beheshti University of Medical Sciences, Faculty of Pharmacy
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-20, 1400/12/01

Expected recruitment end date
2022-09-23, 1401/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Sequential versus Concurrent Albumin and Furosemide in Pediatric Nephrotic Syndrome Patients

Public title
Albumin and Furosemide in Nephrotic Syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 2 to 15 years Diagnosis of Nephrotic Syndrome
Exclusion criteria:

Allergy to Albumin Allergy to Furosemide Urine output less than 0.5 ml/kg/hr

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization has been performed using the block randomization table. In this method, the total study population is divided into small blocks, and randomization is performed inside the block. This method results in more homogeneity between the intervention and control groups. A list of four patient blocks is generated by sealedenvelope.com site is provided to the designated allocation person, in each recruitment the researcher is informed of allocation by telephone.

Blinding (investigator's opinion)

Double blinded

Blinding description

The medication and placebo will be in look-alike coded packages, and the codes based on the block randomization table will be provided to the researcher by a designated person via phone. At the end of the study, after organizing the data by the same person, the statistical expert will perform the analysis. Then, the code packet will be opened, and the final results will be reported.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

institutional ethics committee for Pharmacy, Nursing and Midwifery Schools

Street address

2nd floor, School of Nursing and Midwifery, Valiasr and Niayesh junction

City

Tehran

Province

Tehran

Postal code

1546815514

Approval date

2021-05-29, 1400/03/08

Ethics committee reference number

IR.SBMU.RICH.REC.1400.018

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

Patient weight

Timepoint

24 hours after intervention

Method of measurement

Weighing the patient

2

Description

urine sodium level

Timepoint

24 hours after intervention

Method of measurement

urine analysis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receives a mixture of albumin and furosemide simultaneously. In this group, 10 milligrams of Furosemide is added to a 50 milliliters vial of Albumin 20 percent and for each kilogram of patient weight 5 milliliters would be infused over 1 hour.

Category

Treatment - Drugs

2

Description

Intervention group: Receive Furosemide Upon

completion of albumin. In this group, 5 milliliters of Albumin 20 percent for each kilogram of patient weight is infused over one hour, and after completion of infusion 1 milligram of Furosemide injection would be injected into the patient.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Mofid children's Hospital

Full name of responsible person
Bahador Mirrahimi

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Mofid Children's Hospital, Mirdamad Junction, Shariaty Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Seyed Ali Ziaee

Street address
3rd Floor, Faculty of medicine, Arabi Ave, Daneshjoo Blvd, Velenjak.

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mpd@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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
Islamic Azad University

Full name of responsible person
Fatemeh Tadayoni

Position
pharmacy student

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

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No. 3.1, Shahid Honjani Alley, Shahid Salehi Ave, Abrisham Ave, Shahid Rajaei Blvd, Tehran Town

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Person responsible for scientific inquiries

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Name of organization / entity
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Position
Asistant Profesor, Pharmacotherapy.

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The main outcome will be available.

When the data will become available and for how long
Six months after publishing.

To whom data/document is available
The data will be available per request for people working in academic institutions

Under which criteria data/document could be used
The data will available for using in systematic review and meta-analysis.

From where data/document is obtainable
The data will be available by contacting email; mirrahimi@sbmu.ac.ir.

What processes are involved for a request to access data/document
The data will available for using in systematic review and meta-analysis.

Comments