Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effectiveness of probiotic(lactobacillus reuteri)on the course of the disease and response to treatment of children with nephrotic syndrome.

Protocol summary

Study aim

Determining the effect of probiotics in the treatment of children with nephrotic syndrome

Design

All children aged 2 to 14 years who are referred to the pediatric nephrology clinic of Besat Hospital with a diagnosis of idiopathic nephrotic syndrome are randomly divided into two groups. The first group is treated classically, the second group is treated with probiotics.

Settings and conduct

This one-year research will take place at Besat Hospital's nephrology clinic in Hamadan.After taking the history, physical examination, routine tests and necessary imaging examinations and grouping of patients, the protocols will be implemented.

Participants/Inclusion and exclusion criteria

All children aged 2 to 14 years who are diagnosed with idiopathic nephrotic syndrome are referred to the pediatric nephrology clinic of Besat Hospital and their disease is confirmed by a pediatric nephrologist based on the above criteria. Association with glomerulonephritis (nephrotic nephrotic syndrome) association with renal failure and with hypertension , initiation of antibiotics for any reason, age less than 2 years and more than 14 years and dissatisfaction to participate are excluded from the study

Intervention groups

probiotic is administered orally from rotflore sachet (containing 10 to 8 rotary lactobacilli per sachet) daily

Main outcome variables

Outcome of the disease is defined as recurrence of the disease (proteinuria) or non-recurrence and the course of the disease in terms of response to treatment and the rate of recurrence within 1 year.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210620051628N1**
Registration date: **2021-07-13, 1400/04/22**
Registration timing: **prospective**

Last update: **2021-07-13, 1400/04/22**
Update count: **0**

Registration date

2021-07-13, 1400/04/22

Registrant information

Name

Golamreza Kalvandi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 81 3253 3254

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effectiveness of probiotic(lactobacillus reuteri)on the course of the disease and response to treatment of children with nephrotic syndrome.

Public title
Evaluation of the effect of probiotic prophylaxis in children with nephrotic syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All children 2 to 14 years old who are diagnosed with idiopathic nephrotic syndrome are referred to the pediatric nephrology clinic of Besat Hospital and their disease is approved by a pediatric nephrologist based on diagnostic criteria.

Exclusion criteria:
congenital nephrotic syndrome Secondary nephrotic syndrome Associated with glomerulonephritis (nephrotic nephrotic syndrome) Accompanied by kidney failure Accompanied by high blood pressure Start antibiotics for any reason Age less than 2 years and more than 14 years Dissatisfaction

Age
From **2 years** old to **14 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Alternative block randomization method was used. Random units were children with nephrotic syndrome. R statistical software will be used to generate randomized blocks in this clinical trial. In this software, Blockrand () function was used for random allocation. Using this function, random designs are generated and individuals are assigned to the treatment or control group based on the blocks produced. For example, in the quadruple block of ABAB, the first and third patients to group A, and the second and fourth patients to treatment B. Are allocated. In this study, 12 blocks of 4 will be used. [We have shown the classical therapy group with the symbol "B" and the probiotic therapy group with the symbol "A"]

Blinding (investigator's opinion)
Single blinded

Blinding description
The control group is treated with prednisone. The prednisone and probiotic treatment group, which is similar in structure, shape, color, and odor to the control group, and the drugs are indistinguishable in appearance. Due to the fact that patients are randomly assigned to groups, patients are not aware of the assigned treatment. In this study, participants enter the study based on designated blocks and without knowing the placement in groups. Patients are unaware of being placed in groups, but the facilitator (researcher) is aware of how to place and group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hamadan University of Medical Sciences

Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Blvd

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Hamadan

Province
Hamadan

Postal code
6517838736

Approval date
2021-07-05, 1400/04/14

Ethics committee reference number
IR.UMSHA.REC.1400.308

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
Follow-up of relapse and treatment of patients

Timepoint
MONTHLY

Method of measurement
Presence or absence of proteinuria

Secondary outcomes

1

Description
Recurrence of nephrotic syndrome in treated patients
Timepoint
En MONTHLY
Method of measurement
Presence of protein in urine

Intervention groups

1

Description
Intervention group:probiotic is administered orally from rotflore sachet (containing 10 to 8 rotary lactobacilli per sachet) daily
Category
Prevention

2

Description
Control group: In this group, patients with idiopathic nephrotic syndrome are treated only with classical treatment includes prednisone from Iran Hormone Pharmaceutical Company ,60mg/m2/day
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Nephrology Clinic of Besat Hospital, Hamadan
Full name of responsible person
Farank Heshmati
Street address
Besat Hospital, Hamadan, Shahid Motahari Boulevard
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r.amiri@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Saeed Bashirian
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Gholamreza Kalvandi
Position
Associate Professor of Pediatrics Gastroenterology Department of Pediatrics, School of Medicine Besa
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific

inquiries

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Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Rahimpour Amiri

Position
Assistant Professor of Pediatric Nephrology Department of Pediatrics, School of Medicine Besat Hospi

Latest degree
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Person responsible for updating data

Contact

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Full name of responsible person
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Position
Pediatric resident of Hamadan University of Medical Sciences

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

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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
The results of this study are published in the title of the dissertation and the subsequent paper by Hamadan University of Medical Sciences.

When the data will become available and for how long
From 2023, access was provided.

To whom data/document is available
n Researchers, physicians, nurses and medical students

Under which criteria data/document could be used
En Use the findings to improve patient care and develop research strategies.

From where data/document is obtainable
En Hamadan University of Medical Science

What processes are involved for a request to access data/document
En Consult the Hamadan University of Medical Sciences' Central Library.

Comments