

# 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 rotiflore 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)

##### Phone

+98 81 3253 3254

##### Email address

g.kalvandi@umsha.ac.ir

##### 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

##### City

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 rotiflore 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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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Saeed Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid

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s-bashirian@umsha.ac.ir

**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**

Pediatrics

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**Person responsible for scientific**

## **inquiries**

### **Contact**

**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**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Farank Heshmati

**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**