

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of the effect of probiotic prophylaxis in children with vesicoureteral reflux referred to the pediatric nephrology ward of Hamadan's Besat Hospital, Iran.

Protocol summary

Study aim

The role of probiotic in the medical care of children with VUR.

Design

All children from 2 months to 8 years old are included in the study according to the inclusion criteria. Patients who, according to the pediatric nephrologist, are candidates for medical treatment are randomly divided into two groups. The first group was treated with antibiotic prophylaxis, the second group was 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

Children aged 2 months to 8 years who have been diagnosed with VUR by a pediatric nephrologist. Exclusion criteria: Patients with obstructive causes of VUR, such as congenital obstructive uropathy and acquired obstructive causes of VUR, such as urinary stones and ureteral obstruction due to prior scarring, existence of infectious and inflammatory causes at the same time, any known immune system deficiency, whether congenital or acquired, some metabolic disorders that have been reported and parental dissatisfaction, were excluded.

Intervention groups

Imaging criteria (grading reflux) and nuclear scan findings are used to nominate patients for medical or surgical care. Patients that are candidates for medical attention, according to the pediatric nephrologist, are classified into two classes at random. In the case group (intervention) prescribing probiotics as prophylaxis, Probiotics. In the control group no probiotics and

prophylaxis antibiotics..

Main outcome variables

Outcome of the disease is defined as recurrence of UTI or absence of UTI and the course of the disease will be compared 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: **IRCT20140810018747N1**

Registration date: **2021-06-27, 1400/04/06**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-27, 1400/04/06**

Update count: **0**

Registration date

2021-06-27, 1400/04/06

Registrant information

Name

hassan bazmamoun

Name of organization / entity

Hamadan university of medical sciences

Country

Iran (Islamic Republic of)

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bazmamoun@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of probiotic prophylaxis in children with vesicoureteral reflux referred to the pediatric nephrology ward of Hamadan's Besat Hospital, Iran.

Public title

Evaluation of the effect of probiotic prophylaxis in children with vesicoureteral reflux

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All children 2 months to 8 years old who have been diagnosed with VUR by pediatric nephrologist based on imaging results

Exclusion criteria:

1. Patients with obstructive causes 2. The presence of concomitant infections and inflammation 3. The presence of any known immune system disorders, whether congenital or acquired 4. The presence of any known metabolic disorders.

Age

From 2 months old to 8 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 800

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization method was used. Random units were children with vesicoureteral reflux. "Blockrand()" function in R statistical package was used to generate a block randomization for this clinical trial. This function will randomize subjects to the specified treatments within sequential blocks. Permuted Block Randomization (PBR) consists of 200 blocks with block length 4. Permuted Block Randomization with block length 4 is denoted by PBR(4). In each block of PBR(4) half of the patients are assigned to the treatment groups A and B, respectively. The realization of the above program is as follows: [antibiotic prophylaxis group (B) and probiotic therapy group (A)]

Blinding (investigator's opinion)

Single blinded

Blinding description

Control group with cephalixin capsule, which is odorless

and cream-colored. The probiotic capsule treatment group 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 the placement in groups, but the facilitator (researcher) is aware of the placement and grouping.

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

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Hamadan

Postal code

6517838736.

Approval date

2021-05-02, 1400/02/12

Ethics committee reference number

IR.UMSHA.REC.1400.117

Health conditions studied**1****Description of health condition studied**

Vesicoureteral-reflux

ICD-10 code

N13.732

ICD-10 code description

Vesicoureteral-reflux with reflux nephropathy with hydroureter, bilateral

Primary outcomes**1****Description**

Urinary tract infection recurrence in patients receiving prophylaxis

Timepoint

MONTHLY
Method of measurement
U/A,U/C

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Probiotic administration as prophylaxis, Yumogi probiotic {from Irianik company (Ardifarm Germany) containing Saccharomyces boulardii} with a dose of one 250 mg capsule at the bedtime .

Category

Prevention

2

Description

Control group: no probiotics and prophylaxis antibiotics, prophylaxis with cephalixin (Farabi Pharmaceutical Company) 10 mg per kg body weight, once a day at the bedtime .

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Nephrology Clinic of Besat Hospital, Hamadan

Full name of responsible person

Maryam Emamjamat

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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

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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

Hassan Bazmamoun

Position

Associate Professor of Pediatrics Gastroenterology
Department of Pediatrics, School of Medicine Besa

Latest degree

Subspecialist

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries

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Name of organization / entity

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Rahimpour Amiri

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Assistant Professor of Pediatric Nephrology
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Latest degree

Subspecialist

Other areas of specialty/work

Medical Education

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Pediatric's resident

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

Researchers, physicians, nurses and medical students

Under which criteria data/document could be used

Use the findings to improve patient care and develop research strategies.

From where data/document is obtainable

Hamadan University of Medical Science

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

Consult the Hamadan University of Medical Sciences' Central Library.

Comments