Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of probiotics role in the prevention of urinary tract infection relapse after the first acute uncomplicated pyelonephritis in children

Protocol summary

Study aim

This study emphasizes the prophylactic role of prophylactic probiotics or the reduction of recurrence of urinary tract infections.

Design

Patients who eligible for the study and make signed consent letter are randomly assigned to one of the two groups receiving probiotics or placebo. Patients are evaluated for Pyriorrhea (U / A) and Urinary Cultures (U / C). The urine culture test is positive for more than 10 ^ 4 colony of bacteria (urine culture> 10^ 5 was considered positive but considering that our patients were admitted to the ICU and the catheter The urine was considered to be> 10 ^ 4 positive. Patients are randomly divided into two groups by using the envelope method: Group A Prokid capsule (500mg) containing 3.5x □10□ ^ 9 units Bifid bacterium lactys and 1x □10□ ^ 9 lactobacillus acidophilus and 0.5x □10□ ^ 9 lactobacillus rhamiosus and 1x □10□ ^ 9 units of bifidobacterium bifidum. It is dissolved in water and delivered to the final dose 10 ^ 9 unit/ mL and taken at a dose of 0.5 mL / kg twice daily. Patients in the control group B also receive 0.5 mL / kg of body weight twice a day in pure water.

Settings and conduct

A three-blind parallel study is conducted at Besat Hospital in Sanandaj.

Participants/Inclusion and exclusion criteria

Inclusion criteria: children with acute pyelonephritis (fever above 38 degrees, leukocytosis over 10 thousand and positive culture) without a previous history, age 6 months to 13 years. renal ultrasound performed by a reliable radiologist, hydronephrosis, hypoplasia, cysts or reflux has not been reported. Exclusion criteria: patient and parents dissatisfaction, lack of response to treatment within 48 hours

Intervention groups

Intervention group: Group A or study group are patients who receive probiotics . Control group: the B group or the control group are patients who receive placebo.

Main outcome variables

Recurrence of urinary tract infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141208020249N3**
Registration date: **2018-10-08, 1397/07/16**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-08, 1397/07/16**
Update count: **0**

Registration date

2018-10-08, 1397/07/16

Registrant information

Name

Behzad Khalafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3344 9697

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-17, 1397/03/27

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of probiotics role in the prevention of urinary tract infection relapse after the first acute uncomplicated pyelonephritis in children

Public title
The role of probiotics in urinary tract infections prevention

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Acute pyelonephritis Not history of urinary tract infections Not having urinary re flux Not having genitourinary system structural defects 6 month to 13 years old children

Exclusion criteria:
within 48 hours treatment response failure patient and parents Dissatisfaction

Age
From **6 months** old to **13 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Envelope contains codeBefore starting a study, a series of envelopes are prepared based on the code available on the drug containers. The investigator and the patient are not aware of the concept of the code until the end of the study. Patients will select a package randomly at the time of the first visit and receive the medication.

Blinding (investigator's opinion)
Double blinded

Blinding description
The medicines are packaged and encoded by a pharmacist out of study. Packages are delivered to the pharmacy for distribution to patients. The code on the packets remains outside the study until the analysis of the data is completed.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
pasdaran Blvd, opposite Shadi Hotel, Kurdistan University of Medical Sciences, Sanandaj, Management of Medical Researches and Information. POB 6617713446

City
sanandaj

Province
Kurdistan

Postal code
6617713446

Approval date
2018-08-19, 1397/05/28

Ethics committee reference number
IR.MUK.REC.1397.134

Health conditions studied

1

Description of health condition studied
urinary tract infection

ICD-10 code
N39.0

ICD-10 code description
Urinary tract infection, site not specified

Primary outcomes

1

Description
urinary tract reinfection within 6 months

Timepoint
6 month

Method of measurement
urine culture

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group A or study group are patients who receive probiotics Group A Prokid capsule (500mg) containing 3.5x □10□ ^ 9 units Bifid bacterium lactys and 1x □10□ ^ 9 lactobacillus acidophilus and 0.5x □10□ ^ 9 lactobacillus rhamiosus and 1x □10□ ^ 9 units of bifidobacterium bifidum. It is dissolved in water and delivered to the final dose 10 ^ 9 unit/ mL and taken at a

dose of 0.5 mL / kg twice daily.

Category

Treatment - Drugs

2

Description

Control group: the B group or the control group are patients who receive placebo.Patients in the control group B also receive 0.5 mL / kg of body weight twice a day in pure water.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Rama Naghshizadian

Street address

Vakil Crossroad, Besat Hospital, Department of pediatrric

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Ebrahim Ghaderi

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Sanandaj, Kurdistan University of Medical Sciences, opposite Shadi Hotel, Kurdistan University of Medical Science, POB 6617713446 Management of medical research and information

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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

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Behzad Khalafi

Position

Research Associate, Researcher Soldier General Physician of Kurdistan University of Medical Scien

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Rama Naghshidaian

Position

professor Asistant of Pediatric Nephrology

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Position
Research Associate, Researcher Soldier - General Physician of Kurdistan University of Medical Scien

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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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
All data is from the proposal, raw data and project reports

When the data will become available and for how long
Data is available from the legal system six months after publication for two years

To whom data/document is available
All persons will be able to access the Kurdistan University of Medical Sciences's request to the Kurdistan University of Medical Sciences.

Under which criteria data/document could be used
For legal issues and the need to use data in future studies

From where data/document is obtainable
Rama Naghshizadian

What processes are involved for a request to access data/document
After submitting a request to the Kurdistan Research and Technology Dept. of Science and Technology, a call for submission is given.

Comments