

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The effect of probiotics in the treatment of urinary tract infections in children 6 months to 12 years

Protocol summary

Study aim

Determining the effect of probiotics in the treatment of urinary tract infections in children aged 6 months to 12 years hospitalized in Ayatollah Mousavi Hospital in Zanjan in the period of 2021-2022

Design

Clinical trial with control group, with parallel, randomized, phase 3 groups on 48 patients

Settings and conduct

This study is performed as a clinical trial for 48 patients aged 6 months to 12 years who will be admitted to the pediatric ward of Ayatollah Mousavi Hospital in Zanjan in 2021-2022 due to urinary tract infection as indicated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients 6 months to 12 years with diagnosis of urinary tract infection (urine analysis and positive urine culture), Lack of allergy of the patient to probiotic drug (pedilact), Willingness to participate in the study. Exclusion criteria: renal abnormalities, Having any type of immunodeficiency, Having a UTI and another infectious disease at the same time, Emphysematous pyelonephritis, Allergy to probiotic drug (pedilact) or intolerance to it.

Intervention groups

An intervention group and a control group participated in this study. In the intervention group, in addition to routine treatments, they will receive probiotics for 5 days (5 drops per day for children under 2 years and 15 drops daily for children older than 2 years) and in the control group will receive only routine treatments.

Main outcome variables

Improve the symptoms of urinary tract infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211028052897N1**

Registration date: **2022-03-13, 1400/12/22**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-13, 1400/12/22**

Update count: **0**

Registration date

2022-03-13, 1400/12/22

Registrant information

Name

Mahsa Ansari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3342 2760

Email address

drmahsaansari.9022@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-31, 1400/08/09

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotics in the treatment of urinary tract infections in children 6 months to 12 years

Public title

The effect of probiotics in the treatment of urinary tract infections in children 6 months to 12 years

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients 6 months to 12 years with diagnosis of urinary tract infection (urine analysis and positive urine culture) Lack of allergy of the patient to probiotic drug (pedilact) Willingness to participate in the study

Exclusion criteria:

Renal anomalies Having any type of immunodeficiency Having a UTI and another infectious disease at the same time Emphysematous pyelonephritis Allergy to probiotic drug (pedilact) or intolerance to it

Age

From **6 months** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples Will be selected from 48 patients aged 6 months to 12 years with a diagnosis of urinary tract infection admitted to the pediatric ward in Ayatollah Mousavi Hospital, Zanjan University of Medical Sciences. Individuals are randomly divided into two groups receiving probiotic drug (pedilact) and the control group. Random allocation will be considered as Block permutation Randomization with four blocks including AABB-BBAA-BABA-ABAB-BAAB-ABBA and individuals will be assigned to intervention or control groups based on these blocks (which will be randomly selected).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Deputy of Research and Technology of Zanjan University of Medical Sciences

Street address

Deputy of Research and Technology, third floor, Second building, Central Headquarters of Zanjan University of Medical Sciences, The beginning of

Jomhuri Eslami Boulevard, Azadi Blv, Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2021-08-24, 1400/06/02

Ethics committee reference number

IR.ZUMS.REC.1400.210

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

Improve the symptoms of urinary tract infection

Timepoint

2 and 5 days after starting Probiotic treatment (pedilact)

Method of measurement

Urine culture

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to routine treatments , they will receive probiotics for 5 days (5 drops per day for children under 2 years and 15 drops daily for children older than 2 years).

Category

Treatment - Drugs

2

Description

Control group: They will only receive routine treatments that include intravenous ceftriaxone at a dose of 50 mg / kg / day to 75 mg / kg / day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital

Full name of responsible person

Farzaneh Moezi

Street address

Ayatollah Mousavi Hospital, Gavazang Street, Soboti Blv, Zanzan, Iran

City

Zanzan

Province

Zanzan

Postal code

4513956183

Phone

+98 912 141 1978

Fax

+98 24 3313 1203

Email

moezi@zums.ac.ir

Web page address

http://zums.ac.ir/index.php?slc_lang=fa&sid=19

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanzan University of Medical Sciences

Full name of responsible person

Alireza Shoghli

Street address

Vice chancellor for research, Zanzan University of Medical Sciences, Azadi Blvd. Zanzan

City

Zanzan

Province

Zanzan

Postal code

45154

Phone

+98 24 3315 6477

Fax

+98 24 3315 6770

Email

Research@zums.ac.ir

Web page address

http://zums.ac.ir/index.php?slc_lang=fa&sid=3

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zanzan 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**

Zanzan University of Medical Sciences

Full name of responsible person

Farzaneh Moezi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Ayatollah Mousavi Hospital, Gavazang Street, Pro. Soboti Blv, Zanzan, Iran

City

Zanzan

Province

Zanzan

Postal code

4513956183

Phone

+98 24 3313 0000

Fax

+98 24 3313 1203

Email

moezi@zums.ac.ir

Web page address

http://zums.ac.ir/index.php?slc_lang=fa&sid=19

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Zanzan University of Medical Sciences

Full name of responsible person

Farzaneh Moezi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Ayatollah Mousavi hospital, Gavazang Street, Pro. Soboti Blv, Zanzan, Iran

City

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+98 24 3313 1203

Email

moezi@zums.ac.ir

Web page address

http://zums.ac.ir/index.php?slc_lang=fa&sid=19

Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Mahsa Ansari

Position

Pediatric resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Unit 2 , No. 36 , Middle Fourth (Ebrahim Khani) St.,
Etemadiyeh St., Zanjan

City

Zanjan

Province

Zanjan

Postal code

4515615545

Phone

+98 24 3342 2760

Fax

Email

drmahsaansari.9022@yahoo.com

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

After completing the study, there is a plan to share non-identifiable individual data of the participants, the study protocol, the statistical analysis of the data, the informed consent form patents, clinical reports, analysis codes, and data coding systems (Dictionary).

When the data will become available and for how long

The start of the access period to the data of this study will be from Early 2023 and approximately 6 months after the publication of the results.

To whom data/document is available

The data of this study are possible for all Families of children have a urinary tract infection and are hospitalized in the pediatric ward, and especially those working in health care systems.

Under which criteria data/document could be used

The researcher wants to use the data to improve of children with urinary tract infections.

From where data/document is obtainable

To receive information anyone can be use the following email: moezi@zums.ac.ir

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

After sending the message and introducing herself or himself and the reason for the need for data, the applicant will be provided with the information after confirmation.

Comments