Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparative study of prophylactic effect of probiotic versus placebo on the urinary tract infection in children with the first simple urinary tract infection

Protocol summary

Study aim

Comparative study of prophylactic effect of probiotic and placebo on the incidence of urinary tract infection in children with the first simple urinary tract infection will admitted & refer to pediatric urgence & ward at Khalij Fars Hospital in Bushehr 2019-2020

Design

A clinical trial with 94 patients in two groups; with control group; with parallel groups and unblinded study

Settings and conduct

This will be a prospective, descriptive-analytical study. Children 1 to 12 years of age after recovery from febrile UTI are included in this study. Patients in the probiotic group, daily probiotic containing: 109 colony-forming unit (CFU) (0.5g) / 10 mL of Lactobacillus and Bifidobacterium strains 0.5 mL (25 mg) / kg They receive twice daily (maximum daily dose 20 mL / 1.0g) and patients in the placebo group consume the same amount of water. For this purpose, the contents of each 500 mg capsule are dissolved in 10 ml of sterile water and placed in packs of 100, 200 and 300 cc. (The bacterial count does not change at 10 degrees for 4 weeks.) It is recommended to keep it in the refrigerator. The urine sample is then sent monthly for 6 months via a suprapubic or catheter, with sterile conditions, for urine analysis and culture. If Kant's colony grows, there will be more than 100,000 urinary tract infections.

Participants/Inclusion and exclusion criteria

All 1 to 12 years old children with the first simple urinary tract infection with positive urine culture except for recurrent cases or urinary system abnormalities.

Intervention groups

One group as probiotic recipient to evaluate prophylactic effect and the other group as control with placebo.

Main outcome variables

These studie's findings can be an effective method for prevention of urinary tract infection in children by evaluating the prophylactic effect of probiotics on urinary tract infection and comparing it with placebo.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200202046347N1**
Registration date: **2020-03-20, 1399/01/01**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-20, 1399/01/01**
Update count: **0**

Registration date

2020-03-20, 1399/01/01

Registrant information

Name

Mohamadsaber Moghateli

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 77 3354 8936

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-11, 1398/12/21

Expected recruitment end date

2020-04-09, 1399/01/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of prophylactic effect of probiotic versus placebo on the urinary tract infection in children with the first simple urinary tract infection

Public title

Comparative study of prophylactic effect of probiotic versus placebo on the urinary tract infection in children with the first simple urinary tract infection will admitted & refer to pediatric urgence & ward at Khalij Fars Hospital in Bushehr 2019-2020

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All of 1 to 12 years old children with non-complicated urinary tract infection with positive urine culture

Exclusion criteria:

Age

From **1 year** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization and individual units; statistical software; how to allocate people to two groups by quadruple block method using R software (considering block size: 4 and list length: 94), the target sequences were assigned to two groups . Group A was considered as control group and group B as intervention group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Bushehr University of Medical Sciences

Street address

Boushehr University of Medical Science, Salman Farsi St., Sabzabad Blvd., Boushehr, Iran

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Boushehr

Province

Boushehr

Postal code

7518759577

Approval date

2020-01-01, 1398/10/11

Ethics committee reference number

IR.BPUMS.REC.1398.134

Health conditions studied

1

Description of health condition studied

Preventive effect of probiotic on recurrent urinary tract infection in children

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Comparison of the prophylactic effect of probiotic and placebo on the incidence of urinary tract infection in children with the first simple urinary tract infection

Timepoint

Monthly for six months.

Method of measurement

Take urine samples with sterile conditions using a catheter and send them to the laboratory.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Probiotics recipient; In this group all subjects use probiotic substance called Prokid (developed by Gostaresh Milad Farmed), during that the contents of a capsule dissolve in water every night for six months and then drink it. This will be taught to persons by specialized expertise.

Category

Prevention

2

Description

Control group: Placebo recipient; In this group all subjects use water instead and drink water every night for six months. This will be taught to persons by

specialized expertise.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalij Fars Hospital

Full name of responsible person

Dr Khadijeh Ghasemi

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Dr Azam Amini

Street address

University of Medical Sciences, Moallem St., Bandar Quarter, Boushehr, Iran

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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

Boushehr 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

Boushehr University of Medical Sciences

Full name of responsible person

Mohammad Saber Moghateli

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Latest degree

Subspecialist

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A Level or less

Other areas of specialty/work
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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available