

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparative study of prophylactic antibiotics twice a week with antibiotics every night in recurrent urinary tract infections in children

Protocol summary

Study aim

Comparison of the effect of taking prophylactic antibiotics twice a week with daily in children with recurrent urinary tract infections rate of urinary tract infections in children by taking prophylactic antibiotics every night according to age rate of urinary tract infections by taking prophylactic antibiotics every night by sex rate of urinary tract infections by taking prophylactic antibiotics twice a week by sex rate of urinary tract infections by taking prophylactic antibiotics twice a week according to age

Design

Clinical trial with control group, with parallel Group, non-blind, simple sampling, phase 1 on 60 patients.

Settings and conduct

Children with vesicoureteral reflux who referred to the nephrology of Dr. Sheikh Hospital were selected and divided into control and intervention groups. In both groups, follow-up was performed for ten months. Urine test was taken from the patients on a monthly basis and the recurrence rate of urinary tract infection was evaluated by positive urine culture.

Participants/Inclusion and exclusion criteria

include criteria: Complete the consent form to participate in the project Children with grade 2 or higher reflux who need prophylactic antibiotics Resident of Mashhad or nearby cities that can be followed exclude criteria: Dissatisfaction with continued cooperation Migration Patients with impaired consciousness or mental retardation Patients cared for in orphanages Patients with a history of urinary tract stones History of hypersensitivity reaction to cotrimoxazole or cephalixin Do not refer for testing

Intervention groups

In the intervention group, prophylactic antibiotics were given twice a week of cotrimoxazole at a dose of 5 mg / kg, and in the control group, prophylactic antibiotics were given a single daily dose of cephalixin.

Main outcome variables

Recurrence rate of urinary tract infection was determined by positive urine culture.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201112049368N1**

Registration date: **2020-12-11, 1399/09/21**

Registration timing: **retrospective**

Last update: **2020-12-11, 1399/09/21**

Update count: **0**

Registration date

2020-12-11, 1399/09/21

Registrant information

Name

Amin Taheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5422 2821

Email address

amin.taheri2731@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

2015-07-23, 1394/05/01

Actual recruitment end date

2016-04-20, 1395/02/01

Trial completion date

2017-02-19, 1395/12/01

Scientific title

Comparative study of prophylactic antibiotics twice a week with antibiotics every night in recurrent urinary tract infections in children

Public title

Evaluation of various antibiotic regimens in recurrent urinary tract infections

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Complete the consent form to participate in the project
Children with grade 2 or higher reflux who need prophylactic antibiotics
Patients in good general condition
Resident of Mashhad or nearby cities that can be followed

Exclusion criteria:

Dissatisfaction with continued cooperation
Migration
Patients with impaired consciousness or mental retardation
Patients cared for in orphanages
Patients with a history of urinary tract stones
History of hypersensitivity reaction to cotrimoxazole or cephalixin
Do not refer for testing

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: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description**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 Mashhad University of Medical Sciences

Street address

School of Medicine, Mashhad University of Medical Sciences, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2015-06-22, 1394/04/01

Ethics committee reference number

IR.MUMS.REC.1394.298

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

recurrent urinary tract infections

ICD-10 code

N39.0

ICD-10 code description

Urinary tract infection, site not specified

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

The recurrence rate of urinary tract infection (asymptomatic and symptomatic)

Timepoint

At the beginning of the study and then after receiving antibiotics, once a month for ten months

Method of measurement

Urine culture with more than 10 to the power of 5 colonies

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Consumption of 5 mg/kg cotrimoxazole twice a week for ten months

Category

Prevention

2**Description**

Control group: Consumption of 10 mg/kg cephalixin daily for ten months

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Sheikh Hospital

Full name of responsible person

Amin Taheri

Street address

Sheykh Hospital, Sheykh Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Amin Taheri

Street address

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Web page address

<https://www.mums.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Tehran University of Medical Sciences

Full name of responsible person

Amin Taheri

Position

intern

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available