Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 cephalexin 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 cephalexin.

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 cephalexin 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 cephalexin 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

City
Mashhad

Province
Razavi Khorasan

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9139963185

Phone
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Email
Sheikh.hos@mums.ac.ir

Web page address
https://sheikh.mums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Amin Taheri

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p.relations@mums.ac.ir

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 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