Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The comparison of cefotaxime and ceftriaxone on the duration of diarrhea in children with dysentery

Protocol summary

Summary

Objectives: To compare the effect of cefotaxime and ceftriaxone on the duration of diarrhea and fever in children with dysentery. Design: A single blind randomized clinical trial. Setting and conduct: The eligible patients with complaints of fever and bloody diarrhea hospitalized in pediatrics ward of Shahid Beheshti Hospital will be enrolled into the trial. Inclusion criteria: Age of 2 months to 14 years, having active stool exam. Exclusion criteria: Severe malnutrition, immune deficiency, using of anti-diarrheal drugs. Intervention group: Intravenous infusion of cefotaxime 50 milligram per kilogram of body weight every 8 hours. Control group: Intravenous infusion of ceftriaxone 50 milligram per kilogram of body weight daily. Primary outcome: Duration of diarrhea by studying the stool chart, duration of bloody diarrhea by studying the stool chart, fever with axillary method. Secondary outcome: Duration of hospital stay through counting the days of hospitalization.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102211145N18**
Registration date: **2017-01-08, 1395/10/19**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-01-08, 1395/10/19

Registrant information

Name

Mohammad Reza Sharif

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research and Technology, Kashan University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of cefotaxime and ceftriaxone on the duration of diarrhea in children with dysentery

Public title

The effect of cefotaxime on improvement of pediatric dysentery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 2 months to 12 years; Having active stool exam Exclusion criteria: Severe malnutrition; Immune deficiency; Using of anti-diarrheal drugs

Age

From **2 months** old to **14 years** old

Gender

Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single 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 Kashan University of Medical Sciences
Street address
Kashan University of Medical Sciences, Ghotbe Ravandi Blvd, Kashan, Iran
City
Kashan
Postal code
Approval date
2016-12-07, 1395/09/17
Ethics committee reference number
IR.KAUMS.REC.1395.105

Health conditions studied

1

Description of health condition studied
Dysentery
ICD-10 code
A09.9
ICD-10 code description
Gastroenteritis and colitis of unspecified origin

Primary outcomes

1

Description
Fever
Timepoint
Every 6 hours
Method of measurement
Mercury thermometer with axillary method

2

Description
Duration of bloody diarrhea
Timepoint
Daily
Method of measurement
Stool chart

3

Description
Duration of diarrhea
Timepoint
Daily
Method of measurement
Stool chart

Secondary outcomes

1

Description
Duration of hospital stay
Timepoint
At discharge
Method of measurement
Counting the days of hospitalization

Intervention groups

1

Description
Intervention group: Intravenous infusion of cefotaxime 50 mg/kg every 8 hours
Category
Treatment - Drugs

2

Description
Control group: Intravenous infusion of ceftriaxone 50 mg/kg daily
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Dr. Mohammad Reza Sharif
Street address
Shahid Beheshti Hospital, Ghotbe Ravandi Blvd, Kashan, Iran
City
Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor of Research and Technology, Kashan University of Medical Sciences
Full name of responsible person
Dr. Gholam Ali Hamidi
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Kashan University of Medical Sciences, Ghotbe Ravandi Blvd, Kashan, Iran
City
Kashan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor of Research and Technology, Kashan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Associate Professor, Pediatric Infectious Diseases Subspecialist
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty