

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 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)

Phone

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Email address

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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

Street address

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**

Kashan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Sharif

Position

Associate Professor, Pediatric Infectious Diseases
Subspecialist

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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