

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### The comparison of ciprofloxacin and ceftriaxone on the duration of diarrhea in patients with dysentery

#### Protocol summary

##### Summary

Objectives: To compare the effect of ciprofloxacin and ceftriaxone on the duration of diarrhea and fever in patients with dysentery. Design: A single blind randomized clinical trial. Setting and conduct: The eligible patients with complaints of fever and bloody diarrhea hospitalized in infectious diseases ward of Shahid Beheshti Hospital will be enrolled into the trial. Inclusion criteria: Age of 18 to 75 years, having active stool exam. Exclusion criteria: Severe malnutrition, immune deficiency, using of anti-diarrheal drugs. Intervention group 1: Intravenous infusion of ceftriaxone 1 gram every 12 hours for 5 days. Intervention group 2: Intravenous infusion of ciprofloxacin 400 milligram every 12 hours for 5 days. 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: **IRCT2015061117985N2**

Registration date: **2015-06-24, 1394/04/03**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-06-24, 1394/04/03

##### Registrant information

##### Name

Alireza Sharif

##### Name of organization / entity

Kashan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5554 0026

##### Email address

sharif\_a@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Kashan University of Medical Sciences

##### Expected recruitment start date

2015-06-22, 1394/04/01

##### Expected recruitment end date

2016-06-21, 1395/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The comparison of ciprofloxacin and ceftriaxone on the duration of diarrhea in patients with dysentery

##### Public title

The comparison of ciprofloxacin and ceftriaxone on improvement of dysentery

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 70 years; Having active stool exam Exclusion criteria: Severe malnutrition; Immune deficiency; Using of anti-diarrheal drugs

##### Age

From **18 years** old to **75 years** old

##### Gender

Both

## Phase

3

### Groups that have been masked

No information

### Sample size

Target sample size: 60

### 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

2015-06-10, 1394/03/20

##### Ethics committee reference number

IR.KAUMS.REC.1394.43

## 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 1: Intravenous infusion of ceftriaxone 1 gr every 12 hours for 5 days

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: Intravenous infusion of ciprofloxacin 400 mg every 12 hours for 5 days

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti Hospital

##### Full name of responsible person

Dr. Alireza Sharif

##### Street address

Shahid Beheshti Hospital, Ghotbe Ravandi Blvd, Kashan, Iran

##### City

Kashan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, 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 for research, 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**

## Person responsible for scientific 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

**Other areas of specialty/work****Street address**

Kashan University of Medical Sciences, Ghotbe Ravandi Blvd, Kashan, Iran

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## Person responsible for updating data

**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

**Other areas of specialty/work****Street address**

Kashan University of Medical Sciences, Ghotbe Ravandi Blvd, Kashan, Iran

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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*