

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of cefixime and azithromycin in pediatric dysentery

Protocol summary

Summary

This study was a double-blind randomized clinical study to compare the effects of dysentery cefixime and azithromycin in children. Children 6 months to 12 years as an outpatient with complaints and dysentery (diarrhea with blood and diarrhea as proven by testing) are studied refer to the pediatric clinic of Technology. Patients will be randomly divided into two groups. The first group (58 patients) received azithromycin for five days. The second group (n = 58) as well as the amount of drug cefixime will receive daily. Then all the subjects studied during 14 days of dysentery will improve. Before administration, the patient stool samples for SE (stool test) and SC (stool culture) and antibiogram will be sent to laboratories. Children who have had any underlying disease (such as malabsorption problems, a history of previous prolonged diarrhea, intestinal polyps, malnutrition, impaired immunity, use of probiotic agents, inflammatory bowel disease or chronic inflammatory disease of the small intestine) or A (during one month prior to the study) received antibiotics are not enrolled. The children during the course of antibiotics, along with other diseases or their parents are happy to continue working on the project not be excluded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014091013366N4**

Registration date: **2014-11-08, 1393/08/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-11-08, 1393/08/17

Registrant information

Name

Parsa Yousefi Chaijan

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 1312 1964

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dr.yousefi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2014-07-23, 1393/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of cefixime and azithromycin in pediatric dysentery

Public title

Comparison of cefixime and azithromycin in pediatric dysentery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Children 6 months to 12 years referred to Amir Kabir hospital pediatric clinic complaining of dysentery. Exclusion criteria: malabsorption; previous experience prolonged diarrhea; intestinal polyps; malnutrition; history of immunodeficiency disease of the small intestine combinations of probiotics; inflammatory bowel disease; a history of antibiotic use in the past

month in the course of other diseases; lack of parental consent to continue working.

Age

From **6 months** old to **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Elmol Hoda street

City

Arak

Postal code

Approval date

2012-07-24, 1391/05/03

Ethics committee reference number

91-135-15

Health conditions studied

1

Description of health condition studied

Dysentery

ICD-10 code

A09

ICD-10 code description

Other gastroenteritis and colitis of infectious and unspecified origin

Primary outcomes

1

Description

Stool

Timepoint

On days 3, 7 and 14

Method of measurement

Stool - a stool culture

Secondary outcomes

1

Description

Antibiogram

Timepoint

On days 3, 7 and 14

Method of measurement

Experiment

Intervention groups

1

Description

The first group will receive azithromycin for five days; the first day 12 mg / kg and for the next four days 6 mg / kg .

Category

Treatment - Drugs

2

Description

Group II will receive drug cefixime 8 mg / kg daily.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir Hospital

Full name of responsible person

Dr. Parsa Yousefi

Street address

Amir Kabir Hospital, Railway st.

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Davood Hekmatpoo

Street address

Arak University of Medical Sciences, Elmol Hoda st.

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr. Parsa Yousefi

Position

Assistant Professor of Pediatrics

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Shahram Fazelian

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MD, pediatric residents

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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