

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Evaluation the effect of Montelukast in the treatment of Children with cystitis

Protocol summary

Study aim

Determining the effect of Montelukast in the treatment of children with allergies to cystitis

Design

Clinical trial with control group, randomized, with parallel groups, without blinding, phase 3 on 56 patients, for randomization, block randomization method and online statistical software www.sealedenvelope.com will be used.

Settings and conduct

This study is a randomized clinical trial study that after obtaining the code of ethics from the ethics committee of Arak University of Medical Sciences, will be performed for six months in Amirkabir Hospital in Arak and by easy sampling. Blinding will not be performed in this study. Patients are randomly divided into control and intervention groups if there are inclusion criteria. Then the clinical symptoms of cystitis in patients will be evaluated daily for ten days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: history of allergies, age 5 to 15 years, clinical diagnosis of cystitis. Exclusion criteria: fever, any complications associated with the disease

Intervention groups

In the control group, 28 patients received standard treatment for cystitis as treatment with the cefixime antibiotic at a dose of 8 mg / kg (Sobhan Daroo-Iran) daily for 10 days. In the intervention group, 28 patients received standard cystitis treatment with cefixime antibiotic at a dose of 8 mg / kg daily for 10 days, in addition to the Montelukast (Sobhan Daru-Iran), orally and in the amount of 5 mg per day.

Main outcome variables

Dysuria, frequency, lower abdominal pain, urinary urgency, hematuria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220203053919N1**

Registration date: **2022-02-12, 1400/11/23**

Registration timing: **prospective**

Last update: **2022-02-12, 1400/11/23**

Update count: **0**

Registration date

2022-02-12, 1400/11/23

Registrant information

Name

Mohammadreza Mokhtari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3822 4174

Email address

infa@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-11, 1400/12/20

Expected recruitment end date

2022-03-30, 1401/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of Montelukast in the treatment of Children with cystitis

Public title

The effect of Montelukast in the treatment of cystitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

age 5 to 15 years clinical diagnosis of cystitis History of allergy

Exclusion criteria:

Fever Any complications associated with the disease

Age

From **5 years** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 56 patients with cystitis will be divided into intervention and control groups. Randomization in this study will be performed in 14 blocks of 4 random sequences using block making method and online statistical software www.sealedenvelope.com. Allocation concealment is performing by a number of envelopes with aluminum wrappers (in order not to clarify the contents of the envelopes), they are prepared and each of the random sequences created is registered on a card and the cards are inserted in envelopes. In order to maintain a random sequence, envelopes are numbered in the same way on the outer surface. At the beginning of the study, one of the envelopes is opened in the order of numbering and the assigned group of the participant is revealed based on the order of entry of eligible participants.

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 Arak University of Medical Sciences

Street address

Payambar-e-azam Complex, Sardasht Town

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2022-01-16, 1400/10/26

Ethics committee reference number

IR.ARAKMU.REC.1400.295

Health conditions studied**1****Description of health condition studied**

Cystitis

ICD-10 code

N30

ICD-10 code description

Cystitis

Primary outcomes**1****Description**

Clinical symptoms of cystitis

Timepoint

From the beginning of the intervention on a daily basis for 10 days

Method of measurement

Biography

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: In the control group of 28 patients, only standard treatment of cystitis is prescribed orally with cefixime (Sobhan Daroo-Iran) at a dose of 8 mg / kg daily for 10 days.

Category

Treatment - Drugs

2**Description**

Intervention group: 28 patients in addition to oral treatment with cefixime antibiotic (Sobhan Daru-Iran) at a dose of 8 mg / kg daily for 10 days, Receive oral Montelukast drug (Sobhan Daru-Iran), at a dose of 5 mg daily for 10 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Mohamadreza Mokhtari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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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

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

Arak University of Medical Sciences

Full name of responsible person

Mohamadreza Mokhtari

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available