Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evalution 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
Evalution 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
Street address
Amirkabir hospital, Parastar sq.
City
Arak
Province
Markazi
Postal code
3819693345
Phone
+98 86 3313 4715
Email
info@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
Street address
Payambar-e-azam Complex, Sardasht Town
City
Arak
Province
Markazi
Postal code
3848176341
Phone
+98 86 3417 3639
Email
research@arakmu.ac.ir

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
General Practitioner
Street address
Payambar-e-azam Complex, Sardasht Town
City
Arak
Province
Markazi
Postal code
3848176341
Phone
+98 86 3313 6055
Email
infa@arakmu.ac.ir

Person responsible for scientific 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
General Practitioner
Street address
Payambar-e-azam Complex, Sardasht Town
City
Arak
Province
Markazi
Postal code
3848176341
Phone
+98 86 3313 6055
Email
infa@arakmu.ac.ir

Person responsible for updating data

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
General Practitioner
Street address
Payambar-e-azam Complex, Sardasht Town
City
Arak
Province
Markazi
Postal code
3848176341
Phone
+98 86 3313 6055
Email
infa@arakmu.ac.ir

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