Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of Effect of Montelukast on the Symptoms of Pyelonephritis in Children.

Protocol summary

Study aim
Comparing the effect of Montelukast in the treatment of clinical manifestations of pyelonephritis.

Design
This study is a clinical trial in Phase 4. children who have been diagnosed with pyelonephritis, based on urine test findings and DSMA scans, are selected as the study group. In this study, 100 children who have inclusion criteria are included. Patients are randomly and based on block approach assigned into two groups: 50 children in the intervention group and 50 children in the control group. During the treatment, the symptoms of urination are monitored continuously.

Settings and conduct
This study was carried out as a clinical trial at the Pediatric Clinic of Amir Kabir Hospital in Arak, Also the study will also be single blinded in which patients will be blinded in study.

Participants/Inclusion and exclusion criteria
Patients with pyelonephritis who have clinical symptoms associated with it, according to a certified physician, will be included in this study. Also, children or parents who are reluctant to continue study, will be excluded from our study.

Intervention groups
First group: In the first group, who are taking pyelonephritis usual treatment with montelukast, montelukast is prescribed at a dose of 5 mg / day.
Second group: In the second group of patients taking only pyelonephritis usual treatment.

Main outcome variables
Symptoms of Pyelonephritis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190303042893N1**
Registration date: **2019-03-17, 1397/12/26**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-17, 1397/12/26**
Update count: **0**

Registration date
2019-03-17, 1397/12/26

Registrant information

Name
Tayebe Nazari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-11, 1397/12/20

Expected recruitment end date
2019-05-10, 1398/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of Effect of Montelukast on the Symptoms of Pyelonephritis in Children.

Public title
The effect of Monteluca on the symptoms of pyelonephritis in children

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with pyelonephritis with clinical symptoms of pyelonephritis and satisfaction with the studyThey are selected as the study group. Satisfaction to participate in the study
Exclusion criteria:
Children with underlying illness of kidney, liver and heart.
Age
From **3 years** old to **18 years** old
Gender
Both

Phase
4
Groups that have been masked

- Participant

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomization we will use the block method, Accordingly, the patients under study are divided into two groups. The allocation of patients in two groups was based on demographic characteristics and their matching. Based on this, after considering the patients' demographic data, patients were divided into two equal groups of patients, they enrolled in the study and performed desired intervention on them.
Blinding (investigator's opinion)
Single blinded
Blinding description
This means that patients in groups do not know the used drugs.
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 and Health Services Deputy of research and t
Street address
Student Research Committee, Arak University of Medical Sciences, Arak, Iran
City
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Postal code
3848176941
Approval date
2019-03-04, 1397/12/13
Ethics committee reference number
IR.ARAKMU.REC.1397.304

Health conditions studied

1

Description of health condition studied
Pyelonephritis
ICD-10 code
N10
ICD-10 code description
Acute tubulo-interstitial nephritis

Primary outcomes

1

Description
Symptoms of Pyelonephritis
Timepoint
Before taking the drug and 14 days after taking medication
Method of measurement
Registration of symptoms in the checklist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the first group, Montelukast is prescribed at a dose of 5 mg/day.
Category
Treatment - Drugs

2

Description
Control group: In the first group, only the usual treatments of pyelonephritis is used.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Kabir Hospital

Full name of responsible person
Tayebe nazari
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Sponsors / Funding sources

1

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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
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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