

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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)

Phone

+98 86 3437 0143

Email address

nazaridrt@gmail.com

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 study They 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

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Student Research Committee, Arak University of Medical Sciences, Arak, Iran

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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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Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Hasan Taher Ahmadi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Parsa Yousefi Chayjan

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Medical Education

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

Subspecialist

Other areas of specialty/work

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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