Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative Study of Acetaminophen and Ibuprofen on the Clinical Manifestations of Pyelonephritis in Children.

Protocol summary

Study aim
Comparing the effect of acetaminophen and Ibuprofen 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 Ibuprofen group and 50 children in the acetaminophen 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 Ibuprofen, this drug is prescribed at a dose of 7 mg / kg / day every 6-8 hours. Second group:In the second group of patients taking acetaminophen, this drug is administered at a dose of 10 mg / kg / day every 6-8 hours.

Main outcome variables
Symptoms of Pyelonephritis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130518013366N9**
Registration date: **2018-04-06, 1397/01/17**
Registration timing: **prospective**

Last update: **2018-04-06, 1397/01/17**
Update count: **0**

Registration date
2018-04-06, 1397/01/17

Registrant information

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Parsa Yousefi Chaijan

Name of organization / entity
Arak University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-18, 1397/01/29

Expected recruitment end date
2019-02-18, 1397/11/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative Study of Acetaminophen and Ibuprofen on the Clinical Manifestations of Pyelonephritis in Children.

Public title
Comparison of the effects of acetaminophen and

Ibuprofen on the Clinical Manifestations of Pyelonephritis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with pyelonephritis and referring with related symptoms Satisfaction to participate in the study

Exclusion criteria:

Dissatisfied to participate in the study

Age

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, based on this two lists of patients are provided and each list is placed in one of the groups.

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

Street address

Sardasht

City

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Province

Markazi

Postal code

3848176941

Approval date

2018-02-11, 1396/11/22

Ethics committee reference number

IR.ARAKMU.REC.1396.249

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 1: In the first group, Ibuprofen is prescribed at a dose of 7 mg / kg / day every 6-8 hours.

Category

Treatment - Drugs

2

Description

Intervention group 2: In the second group, acetaminophen is administered at a dose of 10 mg / kg / day every 6-8 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Pediatrics, Amir Kabir Hospital

Full name of responsible person

Dr. Alireza Gholami

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3819693345, Amir Kabir Hospital, Basij Square, Arak.

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Position
Associate Professor of Pediatric Nephrology
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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
Not applicable

Data Dictionary
Not applicable