

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 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

###### Name

Parsa Yousefi Chaijan

###### Name of organization / entity

Arak University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 1312 1964

###### Email address

dr.yousefi@arakmu.ac.ir

##### 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**

Arak

##### **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

##### **Street address**

3819693345, Amir Kabir Hospital, Basij Square, Arak.

##### **City**

Arak

##### **Province**

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##### **Postal code**

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**Phone**

+98 86 3313 5075

**Email**

dralirezagh6363@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Ali Arash Anoushirvani

**Street address**

3819693345, Vice Chancellor for Research, Arak  
University of Medical Sciences, Sardasht, Arak.

**City**

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**Province**

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**Email**

dr.yousefi@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**

Dr. Parsa Yousefichaijan

**Position**

Associate Professor of Pediatric Nephrology

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatric Nephrology

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parsayousefichaijan@yahoo.com

## Person responsible for scientific inquiries

#### Contact

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Arak University of Medical Sciences

**Full name of responsible person**

Dr. Parsa Yousefichaijan

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## Person responsible for updating data

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**Email**

## **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