

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effect of Antihistamines (Diphenhydramine) on Blood Pressure in Children with Common Colds.

#### Protocol summary

##### Summary

Objectives: Hypertension in children is a rare but important complication. The purpose of study is assessing the effect of antihistamines (diphenhydramine) on blood pressure in children with common cold. Design: This study is a clinical trial conducted on children at the age of 2-18 years, suffering from common cold, referred to Amir Kabir Hospital. Setting and conduct: In this study after obtaining informed consent from the children blood pressure will be recorded and then 2-3 days after receiving diphenhydramine syrup, blood pressure will be recorded. If there is hypertension parents must be notified to apply for diagnosis and treatment. This is a one-group before after study. After drug consumption by all patients, blood pressure will be measured for the second time and will be compared with the initial blood pressure. Major eligibility criteria: 110 children with common cold without any underlying problem and any chronic illness are included in the study, and patients who do not agree to participate in the study are excluded from the study There is no control group in this study. Intervention: administration of Diphenhydramine at a dose of 1-5 mg / kg / day. Control group: There is no control group. The main outcome measure variable: blood pressure.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017060413366N8**  
Registration date: **2017-07-02, 1396/04/11**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-07-02, 1396/04/11

#### 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

Vice chancellor for research, Arak University of Medical Sciences

#### Expected recruitment start date

2017-07-06, 1396/04/15

#### Expected recruitment end date

2018-07-06, 1397/04/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The Effect of Antihistamines (Diphenhydramine) on Blood Pressure in Children with Common Colds.

#### Public title

Diphenhydramine Effect on Blood Pressure in Children with Common Colds

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: patients with common colds; 2 to 18 years of age. Exclusion criteria: age lower than 2 years of age; age over 18 years of age; people with underlying

chronic disease: those taking medications affecting blood pressure: people who don't have not consent to the study.

#### Age

From **2 years** old to **18 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **110**

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Single

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethical Committee of Arak University of Medical Sciences

##### Street address

3848176941, Arak University of Medical Sciences, Sardasht, Arak.

##### City

Arak

##### Postal code

3848176941

#### Approval date

2016-07-18, 1395/04/28

#### Ethics committee reference number

IR.ARAKMU.REC.1395.140

## Health conditions studied

### 1

#### Description of health condition studied

Hypertension

#### ICD-10 code

I10

#### ICD-10 code description

High blood pressure

### 2

#### Description of health condition studied

common cold

#### ICD-10 code

J00

#### ICD-10 code description

Nasal catarrh and acute Nasopharyngitis

## Primary outcomes

### 1

#### Description

blood pressure

#### Timepoint

Beginning and end of medical intervention within 72 hours

#### Method of measurement

Blood pressure measurement by researcher

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Diphenhydramine at a dose of 1-5 mg / kg / day for 2-3 days..

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Department of Pediatrics, Amir Kabir Hospital

##### Full name of responsible person

Dr. Parsa Yousefichaijan

##### Street address

3819693345, Amir Kabir Hospital, Basij Square, Arak.

##### City

Arak

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, 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**  
Arak

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Vice chancellor for research, Arak University of Medical Sciences

**Proportion provided by this source**  
100

**Public or private sector**  
*empty*

**Domestic or foreign origin**  
*empty*

**Category of foreign source of funding**  
*empty*

**Country of origin**

**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Amir Kabir Hospital of Arak city

**Full name of responsible person**  
Dr. Parsa Yousefichaijan

**Position**  
Associate Professor of Pediatric Nephrology

**Other areas of specialty/work**

**Street address**  
3819693345, Amir-Kabir Hospital, Basij Square, Arak.

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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parsayousefichaijan@yahoo.com;  
dr.yousefi@arakmu.ac.ir

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## Person responsible for updating data

### 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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**Web page address**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

*empty*

### Study Protocol

*empty*

### Statistical Analysis Plan

*empty*

### Informed Consent Form

*empty*

### Clinical Study Report

*empty*

### Analytic Code

*empty*

### Data Dictionary

*empty*