

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)

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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

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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