

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the effectiveness of a syrup made from sweet Almond in pediatric nocturnal cough with upper respiratory tract infection(common cold) compared to Diphenhydramine: A randomized clinical trial

#### Protocol summary

##### Study aim

Comparision between the effectiveness of a syrup made from sweet Almond with Diphenhydramine in the frequency and severity nocturnal cough due to upper respiratory tract infection (common cold) in children from 2 to 12 years

##### Design

Randomized clinical trials with community-based and pragmatic control group, with parallel groups, without blinding

##### Settings and conduct

Listed 60 patients with cough due to upper respiratory tract infection(common cold) who have entered the research criteria from the Rasul-e-Akram Hospital and Likert scale check list completed and randomly divided into 2 groups of 30 people

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: presence of cough for at most 7 days with or without congestion; fever ( temperature less than 39°); pharyngitis; malaise; headache. Exclusion criteria: presence of asthma; pneumonia; laryngotracheobronchitis; sinusitis; allergic rhinitis; baseline disease; frequent hospitalization; recent consuming of diphenhydramine.

##### Intervention groups

Intervention group: the oral syrup from sweet almond (equivalent to the dose of Diphenhydramine syrup received in the control group: 1 mg/ kg ) will be prescribed in 1 Dose half an hour before bedtime. Control group: Diphenhydramine syrup (Al Havi®) will be prescribed 1 mg/kg/dose in 1 Dose half an hour before bedtime. Duration of treatment is 2 nights in both groups.

##### Main outcome variables

Cough frequency; cough severity; child sleep quality; parents' sleep quality

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180527039867N1**

Registration date: **2018-06-13, 1397/03/23**

Registration timing: **prospective**

Last update: **2018-06-13, 1397/03/23**

Update count: **0**

##### Registration date

2018-06-13, 1397/03/23

##### Registrant information

##### Name

Zahra Karimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5558 0388

##### Email address

karimi.z@tak.iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-23, 1397/06/01

##### Expected recruitment end date

2019-08-23, 1398/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Evaluation of the effectiveness of a syrup made from sweet Almond in pediatric nocturnal cough with upper respiratory tract infection(common cold) compared to Diphenhydramine: A randomized clinical trial

**Public title**

Evaluation the effect of syrup made from sweet Almond in pediatric nocturnal cough

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

The patients's age is two to twelve years old Cough due to upper respiratory tract infection (common cold) for less than 7 days Concomitant symptoms (mild fever: less than 39 ° C, sore throat, cramps, rhinorrhea, mild headache, feeling tired, sneezing Do not use any anti-cough product 18 hours before the intervention Lack of underlying disease (asthma, allergic rhinitis, sinusitis, laryngo tracheobronchitis, congenital heart disease, chronic lung disease, diabetes, kidney disease) Conscious written consciously from parents to enter the study Possibility of patient Follow up

**Exclusion criteria:**

Children with signs and symptoms of asthma, pneumonia, allergic rhinitis, sinusitis, laryngo tracheobronchitis, congenital heart disease, chronic lung disease, diabetes, kidney disease The onset of symptoms of otitis, sinusitis, onset of symptoms of of the lower respiratory tract infection , the addition of a bacterial infection to the viral infection (edema, respiratory problem, severe sore throat with painful ingestion, nausea, vomiting, fever above 39 ° , septic nasal discharge, Facial and peri orbital pain) during the intervention Lack of allergy (presence of symptoms such as i itchy eye & nose, a history of prolonged cold periods,history of repeating similar symptoms, positive family history of allergy, history of drug and food allergy), The presence of sign and symptoms of a Reactive Airway Disease including: tachypnea and tachycardia, short breath, chest tightness ) Getting any anti cough drug before intervention Not using or using irregularly recommended medications Add other cough drugs to treatment during the intervention allergic reaction to drug combinations during the study disrelish to cooperate until the end of the study Inaccessibility of the patient during the study

**Age**

From **2 years** old to **12 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization based on random numbers

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

**Street address**

Fifth Floor, Headquarters, Hemet Highway Between Chamran and Sheikh Fazlullah, Iran University of Medical Sciences

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2018-05-30, 1397/03/09

**Ethics committee reference number**

IR.IUMS.REC 1396.9421309005

**Health conditions studied****1****Description of health condition studied**

Cough due to upper respiratory tract infection(common cold)

**ICD-10 code**

J06

**ICD-10 code description**

Acute nasopharyngitis [common cold]

**Primary outcomes****1****Description**

Cough frequency

**Timepoint**

At the beginning of the study, the first and second day of intervention

**Method of measurement**

Likert scale Checklist

## 2

### **Description**

Cough severity

### **Timepoint**

At the beginning of the study, the first and second day of intervention

### **Method of measurement**

Likert scale Checklist

## 3

### **Description**

Nightly sleep quality of the child

### **Timepoint**

At the beginning of the study, the first and second day of intervention

### **Method of measurement**

Likert scale Checklist

## 4

### **Description**

Nightly sleep quality of the parent

### **Timepoint**

At the beginning of the study, the first and second day of intervention

### **Method of measurement**

Likert scale Checklist

## **Secondary outcomes**

## 1

### **Description**

Time Control Signs

### **Timepoint**

Any time during the study

### **Method of measurement**

Report by the child's parents

## **Intervention groups**

## 1

### **Description**

Intervention group: The oral syrup from sweet almond (equivalent to the dose of Diphenhydramine syrup received in the control group: 1 mg/ kg ) will be prescribed in 1 Dose half an hour before bedtime. Duration of treatment is 2 nights

### **Category**

Treatment - Drugs

## 2

### **Description**

Control group: Diphenhydramine syrup (Al Havi®) will be prescribed 1 mg/kg/day in 1 Dose half an hour before bedtime. Duration of treatment is 2 nights.

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Rasoul-e-Akram Hospital

#### **Full name of responsible person**

Zahra Karimi

#### **Street address**

Sattar Khan St. Mansoori St , Rasoul-e-Akram Hospital

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1445613131

#### **Phone**

+98 21 6651 5001

#### **Email**

karimi.z@tak.iums.ac.ir

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Iran University of Medical Sciences

#### **Full name of responsible person**

Dr. Mazaher Negad

#### **Street address**

Islamic Medicine and Supplement , Institute of Medical History Studies, No. 9, Pirnia Alley, Laleh Zar North Street (Laleh Zar Nou), Islamic Republic. Street,

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1145847111

#### **Phone**

+98 21 5515 2191

#### **Email**

imhicmr@iums.ac.ir

### **Grant name**

### **Grant code / Reference number**

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

Yes

### **Title of funding source**

Iran 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

+98 21 5558 0388

**Email**

o.sadegh33@gmail.com

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Zahra Karimi

**Position**

Iranian medical resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

No. 847 , Vahdat-e-Islami St , South side of Park City ,  
Hassan Abad Square, Behesht Street, Faculty of  
Iranian Medicine

**City**

Tehran

**Province**

Tehran

**Postal code**

114733311

**Phone**

+98 21 5558 0388

**Email**

karimi.z@tak.iums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Omid Sadeghpour

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Faculty of Iranian Medicine, 847, Behesht Street, South  
side of Park City, Vahdat-e-Islami St., Hassan Abad  
Square, tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1114733311

**Phone**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Zahra Karimi

**Position**

Iranian medical resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Faculty of Iranian Medicine, 847, Behesht Street, South  
side of Park City, Vahdat-e-Islami St., Hassan Abad  
Square, tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1114733311

**Phone**

+98 21 5558 0388

**Email**

karimi.z@tak.iums.ac.ir

## 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