

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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