Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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

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Iran (Islamic Republic of)

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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

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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
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Sponsors / Funding sources

1

Sponsor
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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

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

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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