Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison Study of Honey versus Diphenhydramine Effect on Cough Alleviation in 2-5 Years Old Children with Viral Upper Respiratory Tract Infection

Protocol summary

Summary

Background & purpose: Viral upper respiratory tract infection and cold drugs consumption in children is widespread, These drugs may not only have no effect on disease improvement, but also have many side effects. The purpose of this study was comparison of honey compare with diphehydramine effect in the alleviation of cough in children trial after 2 days of treatment, including severity and frequency remission rates. Materials and Methods: In a double blind clinical trial study, which was conducted in 1389 at the pediatric clinic of Shariati Hospital in Bandar Abbas city, among children two to five years with symptoms of acute cough associated with viral upper respiratory tract infection symptoms, 170 children were selected and after applying the exclusion criteria (involving other parts of the respiratory system, adding a bacterial infection ...) 126 children remained in the study. The patients divided into two groups receiving honey and diphenhydramine. Two days later second examination was done and number and severity of cough in night and day was evaluated. The number and severity of nocturnal cough were compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110247882N1**
Registration date: **2012-11-27, 1391/09/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-11-27, 1391/09/07

Registrant information

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Recruitment status

Recruitment complete

Funding source

Hormozgan University of Medical Sciences(HUMS)/ Researcher

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-03-21, 1390/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Study of Honey versus Diphenhydramine Effect on Cough Alleviation in 2-5 Years Old Children with Viral Upper Respiratory Tract Infection

Public title

Honey effect on cough alleviation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:The patients's age is two to five years

old; Acute cough is the chief complaint;The symptoms of viral upper respiratory tract infection are the only concomitant symptoms [fever (oral temperature from 37.8to 38.5 or axillary temp from 37.2 to 37.9) rhinorrhea , sneezing, blocked nose, sore throat, cough, mild headache, restlessness, hoarseness];The patient has been brought to clinic at first or second day of begining cough;The patient has not bacterial infections symptoms of upper respiratory tract (moderate to high fever, sever sore throat with painful swallowing, severe headache, nausea, vomiting, abdominal pain, ...);The patient has not the symptoms of lower respiratory tract infection (high fever, chills, dyspnea, malaise, pleuritic chest pain, tachypnea, retraction); There are not associated infections such as otitis and sinusitis; Allergy is not considered (associated symptoms such as itchy eye & nose, history of repeating similar symptoms, a history of prolonged cold periods, positive family history; The patient has not signs of Reactive Airway Disease (wheezing, shortness of breath,pressure or tightness feeling in chest , tachypnea, tachycardia); The parents have not begun any drug before coming to clinic . Exclusion criteria were: Onset of otitis or sinusitis symptoms; Onset of symptoms of lower respiratory tract involvement; Adding a bacterial infection, (purulent nasal discharge, high fever, difficulty breathing, Periorbital edema, facial pain); Not using of recommended treatments; Adding other drugs to recommended treatment; Non-coordinated reports of persons who take care of patients.

Age
From **2 years** old to **5 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **126**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Hormozgan university of Medical Sciences

Street address
Ostandari Blv

City
Bandar Abbas

Postal code

Approval date
2012-07-29, 1391/05/08

Ethics committee reference number
hec-91-5-1

Health conditions studied

1

Description of health condition studied
Common Cold

ICD-10 code
J00

ICD-10 code description
Acute nasopharyngitis

Primary outcomes

1

Description
Number of Night cough

Timepoint
Before intervention, 48 h after intervention

Method of measurement
Visual scale of the number of coughs

2

Description
Severity of night cough

Timepoint
Before intervention, 48 h after intervention

Method of measurement
Visual scale of severity of coughs

3

Description
The number of daily cough

Timepoint
Before intervention, 48 h after intervention

Method of measurement
Visual scale of the number of coughs

4

Description
severity of daily cough

Timepoint
Before intervention, 48 h after intervention

Method of measurement
Visual scale of severity of cough

Secondary outcomes

empty

Intervention groups

1

Description
Diphenhydramin syrup, 5mg/kg/TDS,for 48 h
Category
Treatment - Drugs

2

Description
Honey with the same volume and frequency and duration of use with diphenhydramine
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr Ali Shariatee Hospital
Full name of responsible person
Dr. Mahshid Ahmadi, Pediatrician, Assisstant professor
Street address
Shaheed Naser Blv
City
Bandar Abbas

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hormozgan University of Medical Sciences(HUMS)
Full name of responsible person
Mrs Ghasemi
Street address
Ostandari Blv
City
Bandar Abbas
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hormozgan University of Medical Sciences(HUMS)
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

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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