

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

Mahshid Ahmadi

Name of organization / entity

Mazandaran University of Medical Sciences

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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

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Mahshid Ahmadi

Position

Pediatrician/Assisstant professor

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