Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effect of Two Kinds of Iranian Honey and Diphenhydramine on Nocturnal Cough and Sleep Quality in Coughing Children and Their Parents

Protocol summary

Summary

Objectives: The aim of this study is the comparison of the effect of honey and diphenhydramine on children's nocturnal cough and sleep quality in coughing children and their parents. Design: In the present study, 150 children with nocturnal viral cough are chosen and will be divided randomly into 3 groups: 2 Honey groups (type 1 and 2) and Diphenhydramine group. Setting and conduct: Before starting the treatment, a questionnaire with 5 questions about children’s nocturnal cough and the quality of night sleep (both in children and their parents) will be given to the parents. After two days of treatment (honey or diphenhydramine) the same questionnaire will be completed by calling parents. Major Inclusion and Exclusion criteria: The presence of nocturnal viral cough during the last week and absence of pnemonia and asthma symptoms and baseline disease. Intervention: Recieving honey or diphenhydramine Main outcome measures (variables): Finally the first and second answers will be compared to each other for comparison of the effect of honeys and diphenhydramine on the severity and frequency and bothering of children's nocturnal cough.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014090819037N1**
Registration date: **2014-10-10, 1393/07/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-10-10, 1393/07/18

Registrant information

Name
Mahdieh Yousef-Zanjani
Name of organization / entity
Qazvin University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 28 3333 6004
Email address
yusefi.mahdieh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Qazvin university of medical sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-10-23, 1393/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Two Kinds of Iranian Honey and Diphenhydramine on Nocturnal Cough and Sleep Quality in Coughing Children and Their Parents

Public title

Comparison of the Effect of Honey and Diphenhydramine on Children's Nocturnal Cough and Sleep Quality

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Presence of cough with or without

rhinorrhea for at most 7 days; Congestion; fever (oral 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

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

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The patients who come to the pediatrics clinic will be randomly selected for each groups of the study by Random Allocation.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Qazvin university of medical sciences

Street address
Shahid Bahonar blv.

City
Qazvin

Postal code

Approval date
2013-10-15, 1392/07/23

Ethics committee reference number
28.20.7932

Health conditions studied

1

Description of health condition studied
nocturnal cough due to acute upper respiratory tract infection

ICD-10 code
J06.9

ICD-10 code description
upper respiratory infection (acute)

Primary outcomes

1

Description
Severity of children's nocturnal cough

Timepoint
up to 48 hours of treatment

Method of measurement
Same questionnaire before and after the treatment

2

Description
Frequency of children's nocturnal cough

Timepoint
up to 48 hours of treatment

Method of measurement
Same questionnaire before and after the treatment

3

Description
The bothersome nature of children's nocturnal cough

Timepoint
up to 48 hours of treatment

Method of measurement
Same questionnaire before and after the treatment

Secondary outcomes

1

Description
The quality of nocturnal sleep in patients' parents

Timepoint
up to 48 hours of treatment

Method of measurement
Same questionnaire before and after the treatment

2

Description
The quality of nocturnal sleep in patients

Timepoint
up to 48 hours of treatment

Method of measurement
Same questionnaire before and after the treatment

Intervention groups

1

Description
Control group: Oral solution of Diphenhydramine HCl from Ramopharmin drug manufacturing company, Tehran, Iran, registered No. 1228056772 (Patients in this group receive their treatments within 30 minutes before

going to sleep at two subsequent nights (two doses). Dosage: children aged 2 to 6 years receive 6.25 mg/dose (2.5 mL), children aged 6 to 12 years receive 12.5 mg/dose (5 mL)).

Category

Treatment - Drugs

2

Description

First intervention group Kimia Honey from Kimia company, Ardabil, Iran, registered No. 4916 (Patients in this group receive their treatments within 30 minutes before going to sleep at two subsequent nights (two doses). Dosage: children aged 2 to 6 years receive 6.25 mg/dose (2.5 mL), children aged 6 to 12 years receive 12.5 mg/dose (5 mL)).

Category

Treatment - Drugs

3

Description

Second intervention group: ShahdeGolha Honey from ShahdeGolha company, Khorasan-e Razavi, Iran, registered No. 73294 (Patients in this group receive their treatments within 30 minutes before going to sleep at two subsequent nights (two doses). Dosage: children aged 2 to 6 years receive 6.25 mg/dose (2.5 mL), children aged 6 to 12 years receive 12.5 mg/dose (5 mL)).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qods Pediatrics Hspital

Full name of responsible person

Dr. Parviz Ayazi

Street address

Qods Square

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Qazvin University of Medical Sciences

Full name of responsible person

Dr. Taghi Naserpour

Street address

Shahid Bahonar Boulevard

City

Qazvin

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for Research, Qazvin University of Medical Sciences

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mahdieh Yousef-Zanjani

Position

Medical Student

Other areas of specialty/work

Street address

Shahid Bahonar Boulevard

City

Qazvin

Postal code

Phone

+98 912 614 3161

Fax

Email

yusefi.mahdieh@yahoo.com

Web page address

Person responsible for updating data

Contact

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