Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Cordia Myxa,s herbal syrup and Diphenhydramine in the treatment of dry cough

Protocol summary

Study aim
A Comparative Study on the Effect of Cordia Myxa,s herbal syrup and Diphenhydramine Syrup on the Treatment of Dry Coughing Patients

Design
To compare the intervention and control groups, we divided Abuzar Hospital patients to 62 member groups who are given Cordia myxa´s herbal syrup and Diphenhydramine compound respectively.

Settings and conduct
Patients with dry cough referred to Abouzar Children's Hospital by dividing them into two intervention and control groups and receiving the relevant drug that the researcher and the volunteer participated in this study are completely unaware until the last stage of extracting the final information. The Diphenhydramine and Cordia Myxa,s herbal syrup have the same appearance. Two syrups at a dose of 5 mg / kg / day are given in four divided doses. After 72 hours of the initial visit, the number and severity of the patients' night and day cough are compared with the first day.

Participants/Inclusion and exclusion criteria
Inclusion criteria: - Children aged 6-12 years, with acute cough and without foreign body aspiration along with mild fever, rhinorrhea, sneezing, mild sore throat, mild headache, mild nasal obstruction, hoarseness and conjunctivitis. Excusion criteria: 1- The existence of bacterial infection of the upper respiratory tract, mild fever to severe fever, sore throat, nausea, vomiting, abdominal pain and severe headaches 2- Inferior respiratory tract infections, cough, shortness of breath, malaise, chest pain, and Tachypnea 3- Drug intake before referral arbitrarily 4- Start the symptoms of otitis or sinusitis 5- Start the symptoms of lower respiratory problems 6- Avoid using recommended treatments 7- Add another drugs to the recommended treatment

Intervention groups
Intervention group: Diphenhydramine Compound Control group: Cordia Myxa,s herbal syrup

Main outcome variables
dry cough condition

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170809035599N1**
Registration date: **2019-02-19, 1397/11/30**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-19, 1397/11/30**
Update count: **0**

Registration date
2019-02-19, 1397/11/30

Registrant information

Name
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Name of organization / entity
Ahvaz Jundishapur University of Medical Science

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-11, 1397/08/20

Expected recruitment end date
2019-03-11, 1397/12/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Cordia Myxa,s herbal syrup and Diphenhydramine in the treatment of dry cough

Public title

Effect of Cordia Myxa,s herbal syrup on the Treatment of Dry Coughing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged 6-12 years who referred to the clinic with the main complaint of acute cough and without foreign body aspiration on the first or second day of coughing. The associated symptoms include upper respiratory tract infections, mild fever (oral temperature 37.8-38.3), rhinorrhea, sneezing, mild sore throat, mild headache, Mild nasal congestion, hoarse voice, conjunctivitis.

Exclusion criteria:

Symptoms of bacterial infection of the upper respiratory tract: middle to sever fever, severe sore throat with ingestion, nausea, vomiting, abdominal pain and severe headache. The presence of symptoms of lower respiratory tract infection: high fever, cough, dyspnea, boredom, chest pain and tachypnea pain. The presence of symptoms of airway reactions including wheezing, tachypnea, dyspnea. Signs of allergy such as the presence of symptoms of nose and eye itching, or a history of repetitions of similar symptoms and outer body spiration. Avoid taking medication before referral Start the symptoms of otitis or sinusitis. Start symptoms of low respiratory involvement.

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, both Diphenhydramine and Cordia Myxa,s herbal syrup are packed in the same boxes. Different serial numbers are placed on the boxes where the medications can be separated. We use simple randomization model using random number table (computer randomization method). The advantages of this kind of randomization are that the type of treatment allocated to the two groups is totally unpredictable and, according to the theory of probabilities, it can be guaranteed that in a large number, the sample size of the study will be similar in the intervention and control groups. It should be noted, that the implementation of this method is very simple. Since we have a complete list of elements that constitute the population, we use individual sampling. In this research, we use a randomized numbers table as randomization method, which is a computational method for generating a sequence of numbers that do not have a specific pattern. A random number is a mode of possible state that is selected during a random event. This method starts with a random initial number (core). Then we put this number into power 2 and select its middle numbers. The number of selected numbers is equal to the number of core digits. Then, after putting the zero point at the beginning of the generated middle number, the random number is obtained and according to the specific mathematical algorithm, the sequence numbers are generated. Any number is independent from other numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

the researcher and the volunteer participate in this study are completely unaware of the final stage of extracting the final information from the drugs that are presented separately by the pharmacist which are identical in appearance were placed in identical bottles.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Golestan

City

Ahvaz

Province

Khouzestan

Postal code

15794-61357

Approval date

2018-01-16, 1396/10/26

Ethics committee reference number

IR.AJUMS.REC.1396.882

Health conditions studied

1

Description of health condition studied
dry cough
ICD-10 code
R05
ICD-10 code description
Cough

Primary outcomes

1

Description
cough
Timepoint
One day before the intervention and three days after the intervention began
Method of measurement
The number and severity of patients' night and day coughing

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The recipients of Cordia Myxa,s herbal syrup (62 patients)Cordia Myxa,s herbal syrup produced in pharmaceutical technology incubator of Ahvaz jundishapur University of medical sciences. Dosage: 5mg/kg/day in 4 divided doses (orally). Survey: after 72 hours from initial intervention, the number and severity of patients night and day cough will check.
Category
Treatment - Drugs

2

Description
Control group: The recipients of Diphenhydramine syrup (62 patients)Diphenhydramine syrup produced in Alborz Darou Pharmaceuticals Company.Dosage: 5mg/kg/day in 4 divided doses (orally).Survey: after 72 hours from initial intervention, the number and severity of patients night and day cough will check.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Abuzar Hospital
Full name of responsible person
Dr. Amanollah Zarei Ahmady
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
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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
Ahvaz 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available