Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

The effect of compound honey syrup on clinical manifestations of chronic sinusitis in cystic fibrosis (CF) patients

Protocol summary

Study aim
The effect of compound honey syrup on clinical manifestations of chronic sinusitis in cystic fibrosis (CF) patients

Design
This study is a double-blind randomized clinical trial with a sample size of 40 cases.

Settings and conduct
This double-blind study is performed in the lung clinic of Mofid Children's Hospital in Tehran. At the first visit, the relevant questionnaires are completed and the examination is performed by the pulmonary specialist. All standard medications are prescribed. The patient is followed up by phone in the second, fourth, eighth and tenth weeks and in the sixth week, re-examination, control of drug side effects, filling out the questionnaire, re-administration of the drugs are performed. Finally, in the twelfth week, the final visit will be made and the questionnaires will be completed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with cystic fibrosis with clinical signs of sinusitis over 6 years of age who refer to the pulmonary clinic of Mofid Children's Hospital and if they receive informed consent from the parents of children and children over 6 years old Criteria for not entering: Patients with cystic fibrosis under 6 years of age, lack of clinical signs of sinusitis, patients in need of hospitalization and patients with underlying conditions such as allergic bronchopulmonary aspergillosis (ABPA) and Tuberculosis

Intervention groups
All standard and required drugs are prescribed to the patient and in the experimental group, in addition to the above treatments, combined honey syrup and in the control group, the placebo is also prescribed. Consumption of compound honey syrup and placebo, 5-10 cc (according to the weight of children) in 100 cc of boiled and lukewarm water twice a day 30 minutes after meal.

Main outcome variables
Runny nose ,Nasal obstruction ,Ear fullness ,Dizziness ,Ear pain ,Facial pain/pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201009048976N1**
Registration date: **2021-01-23, 1399/11/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-23, 1399/11/04**
Update count: **0**

Registration date
2021-01-23, 1399/11/04

Registrant information

Name
Samira Borhani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2255 5872

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01

Expected recruitment end date
2022-02-20, 1400/12/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of compound honey syrup on clinical manifestations of chronic sinusitis in cystic fibrosis (CF) patients

Public title

The effect of compound honey syrup on chronic sinusitis in cystic fibrosis patients

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with cystic fibrosis with clinical signs of sinusitis over 6 years of age who refer to the pulmonary Clinic of Mofid Children's Hospital and enter the study with the informed consent of the parents of children and children over 6 years of age.

Exclusion criteria:

Patients with cystic fibrosis under 6 years of age referred to the pulmonary Clinic of the Mofid Children's Hospital, lack of clinical signs of sinusitis, patients in need of hospitalization and patients with increased cough, sputum and fever, and patients with underlying conditions such as allergic bronchopulmonary aspergillosis(ABPA) and Tuberculosis are not included in the study.

Age

From **6 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is based on a table of random numbers and blocks of 4 and the study is double-blind.

Blinding (investigator's opinion)

Double blinded

Blinding description

The compound honey syrup and placebo have been coded for blinding. The patient and researcher are unaware of the type of drug administered.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak, Yaman Ave., Sh. Aarabi Ave., Shahid Beheshti University of Medical Sciences

City

tehran

Province

Tehran

Postal code

1985717443

Approval date

2020-04-19, 1399/01/31

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.441

Health conditions studied

1

Description of health condition studied

cystic fibrosis

ICD-10 code

E84

ICD-10 code description

Cystic fibrosis

Primary outcomes

1

Description

Runny nose

Timepoint

At the beginning of the study(Before starting the intervention), the end of the Sixth and twelfth week

Method of measurement

SNOT questionnair

2

Description

Nasal obstruction

Timepoint

At the beginning of the study, the end of the Sixth and twelfth week

Method of measurement

SNOT questionnair

3

Description

Ear fullness

Timepoint

At the beginning of the study, the end of the Sixth and twelfth week

Method of measurement
SNOT questionnair

4

Description
Dizziness
Timepoint
At the beginning of the study, the end of the Sixth and twelfth week
Method of measurement
SNOT questionnair

5

Description
Ear pain
Timepoint
At the beginning of the study, the end of the Sixth and twelfth week
Method of measurement
SNOT questionnair

6

Description
Facial pain/pressure
Timepoint
At the beginning of the study, the end of the Sixth and twelfth week
Method of measurement
SNOT questionnair

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to all the standard and required medicines for the patient, in the experimental group, compound honey syrup is also prescribed. Consumption of compound honey syrup, 5-10 cc (according to the weight of children, in the weight of over 30 kg, 10 cc and in the low weight of 30 kg, 5 cc) in 100 cc of boiled and lukewarm twice a day 30 minutes after the meal. The study period is 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: In addition to all the standard and required drugs for the patient, in the control group, placebo approved by the pharmaceutical group (containing sodium saccharin) is also prescribed. Consumption of placebo syrup is 5-10 cc (according to the weight of children, in the weight of over 30 kg, 10 cc and in the low weight of 30 kg, 5 cc) in 100 cc of boiled and lukewarm water twice a day 30 minutes after the meal.The study period is 12 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mofid pediatric hospital
Full name of responsible person
samiraborhani
Street address
Mofid pediatric hospital, Shariati Ave, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sponsor Vice chancellor for research, Shahid Beheshti University of Medical Sciences
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
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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
Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

samiraborhani

Position

MD, PhD student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Publishing results in the form of a Ph.D. thesis and an article indexing in ISI

When the data will become available and for how long

After PhD thesis defence

To whom data/document is available

Public

Under which criteria data/document could be used

For research reasons

From where data/document is obtainable

Shahid Beheshti University of Medical Sciences

What processes are involved for a request to access data/document

Approval of the relevant responsible

Comments