Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

The efficacy of compound honey syrup on Fractional exhalation Nitric Oxide (FeNO) changes in Cystic Fibrosis patients

Protocol summary

Study aim
Evaluation of the effect of compound honey syrup on Fractional exhalation Nitric Oxide (FeNO) changes in Cystic Fibrosis patients

Design
An intervention study of before-after clinical trials and a sample size of 30 people.

Settings and conduct
This project will be done in Mofid Children's Hospital in Tehran and the study will be performed as a before-after Clinical Trial.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All patients with cystic fibrosis over 6 years of age who are referred to the pulmonary Clinic of Mofid Children's Hospital, who have been diagnosed by a pediatric lung specialist and will enter the study with the informed consent of the parents of children and children over 6 years old. Exclusion criteria: Patients with cystic fibrosis under 6 years of age referred to the pulmonary clinic of a children's hospital, patients in need of hospitalization, and patients with a disease attack (increased cough, sputum, fever, and need for hospitalization); patients with underlying diseases such as allergic bronchopulmonary aspergillosis, heart failure, and tuberculosis; patients who develop other acute illnesses during treatment, patients who are allergic to any of the components of the compound honey syrup, and patients who have decided to leave the study at their own request. Patients who are unable to cooperate in performing the FeNO test.

Intervention groups
After obtaining informed consent, all standard and required medications are prescribed for the patient also the compound honey syrup is prescribed. Consumption of this syrup is 5-10 cc (depending on the age and weight of children) in 100 CC of boiled and lukewarm water twice a day 30 minutes after a meal for 12 weeks.

Main outcome variables
Fractional exhalation Nitric Oxide, weight, height, body mass index, Staphylococcus aureus and Pseudomonas aeruginosa culture

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200428047229N2**
Registration date: **2020-07-15, 1399/04/25**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-15, 1399/04/25**
Update count: **0**

Registration date
2020-07-15, 1399/04/25

Registrant information

Name
Hanieh Tahermohammadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-29, 1399/04/09

Expected recruitment end date
2020-12-29, 1399/10/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The efficacy of compound honey syrup on Fractional exhalation Nitric Oxide (FeNO) changes in Cystic Fibrosis patients

Public title
The effect of compound honey syrup on the airways of cystic fibrosis patients Fractional exhalation Nitric Oxide

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All cystic fibrosis patients over 6 years of age should be referred to the pulmonary clinic of Mofid Children's Hospital, diagnosed by a pediatric lung specialist. Conscious consent of parents of children and children over 6 years of age

Exclusion criteria:
Cystic fibrosis patients under 6 years of age referred to the pulmonary clinic of Mofid Children's Hospital Patients in need of hospitalization Patients who have attack symptoms of the disease (increased cough, sputum, fever, and need for hospitalization). Patients with underlying diseases such as allergic bronchopulmonary aspergillosis, heart failure and tuberculosis. Patients with other acute illnesses during treatment. Patients who are allergic to any of the components of the compound honey syrup. Patients who have decided to leave the study at their own request. Patients who are unable to co-operate with the FeNO test.

Age
From **6 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی شهید بهشتی

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Approval date
2020-06-28, 1399/04/08

Ethics committee reference number
IR.SBMU.RETECH.REC.1399.279

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
Fractional exhalation Nitric Oxide

Timepoint
At the beginning of the study (before the start of the intervention) and the twelfth week after the start of the compound honey syrup

Method of measurement
FeNO monitor (NObreath®)

Secondary outcomes

1

Description
Weight

Timepoint
At the beginning of the study (before the start of the intervention) and the twelfth week after the start of the compound honey syrup

Method of measurement
Scales

2

Description
Height

Timepoint
At the beginning of the study (before the start of the intervention) and the twelfth week after the start of the

compound honey syrup

Method of measurement

Standing position and by meters

3

Description

Body Mass Index (BMI)

Timepoint

At the beginning of the study (before the start of the intervention) and the twelfth week after the start of the compound honey syrup

Method of measurement

Weight/(height)2

4

Description

Staphylococcus aureus bacterial culture

Timepoint

At the beginning of the study (before the start of the intervention) and the twelfth week after the start of the compound honey syrup

Method of measurement

Preparation of sputum or throat swab after chest physiotherapy in the absence of sputum

5

Description

Pseudomonas aeruginosa bacterial culture

Timepoint

At the beginning of the study (before the start of the intervention) and the twelfth week after the start of the compound honey syrup

Method of measurement

Preparation of sputum or throat swab after chest physiotherapy in the absence of sputum

Intervention groups

1

Description

Intervention group: After receiving informed consent from the parents of patients and children over 6 years of age, all standard and required drugs for cystic fibrosis patients are prescribed and in addition to the above treatments, the compound honey syrup is also prescribed. In the first visit (before starting the syrup) FeNO test, weight and height are taken from the patients and sputum culture is requested. Then compound honey syrup, 5-10 cc (depending on the age and weight of children) in 100 CC of boiled and lukewarm water is administered twice a day for 30 minutes after a meal for 6 weeks, and in weeks 2 and 4, the patient is followed up for the correct use of the drug. At 6 weeks, the patient is visited again, and the drugs and syrup are prescribed again for 6 weeks, and after that, the patient is followed up in the 8th and 10th weeks in terms of proper drug use. Finally, The patient is visited again in the 12th week, and FeNO test, weight and height are taken from the patients and also sputum culture is requested.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid children's hospital

Full name of responsible person

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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

Tehran - Shahid Beheshti University of Medical Sciences, Next to Taleghani Hospital, Yemen St., Chamran Highway

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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
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Assistant of Traditional Medicine
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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, an article indexing in ISI, and an article indexing in Pub Med
When the data will become available and for how long
After Ph.D. thesis defense
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
Approving by the responsible officer
Comments