Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

The efficacy of Compound Honey Syrup on Fractional Exhalation Nitric Oxide (FeNO) Changes, Pulmonary Symptoms and Body Mass Index (BMI) in Cystic Fibrosis Patients

Protocol summary

Study aim

The efficacy of compound honey syrup on fractional exhaled nitric oxide (FeNO) changes, pulmonary symptoms and body mass index in patients with cystic fibrosis

Design

A clinical trial, without control group and blinding in 40 cystic fibrosis patients over 6 years, and follow up for three months To check the effect of the drug

Settings and conduct

patients 6 years and older with fibrocystic cysts referred to the pulmonary clinic of Mofid Hospital in 2019 and 2020.after obtaining the consent, the demographic characteristics questionnaire and the CFQ-R questionnaire for the patient are completed.FeNO test and recorded BMI measurements Then the necessary standard treatments and in addition compound honey syrup are prescribed.The method of use and possible side effects and how to contact the researcher are fully explained.Then the information is analyzed before and after starting the treatment with syrup.

Participants/Inclusion and exclusion criteria

All patients with cystic fibrosis older than 6 years referred to the Lung Clinic of Mofid Children Hospital who are able to perform FeNO testing are enrolled if informed consent is obtained from parents and children. Exclusion criteria: Patients with cystic fibrosis under 6 years of age referring to Pediatric Hospital Lung Clinic, patients in need of hospitalization and patients who have exacerbation , patients with underlying diseases such as allergic bronchopulmonary aspergillosis , Patients with another acute illness during treatment, patients who are sensitive to each component of the compound honey syrup, and patients who wish to withdraw from the study. Patients unable to perform FeNO test.

Intervention groups

Administration of compound honey syrup in cystic fibrosis patients to evaluate its effect on FeNO, pulmonary symptoms and Body Mass Index

Main outcome variables

Weezing, daily cough, sputum production, difficulty breathing,BMI، FeNO

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200103045989N1**
Registration date: **2021-12-21, 1400/09/30**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-21, 1400/09/30**
Update count: **0**

Registration date

2021-12-21, 1400/09/30

Registrant information

Name

Nafise Fadavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3230 2382

Email address

nf.fadavi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2022-08-06, 1401/05/15

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, Pulmonary Symptoms and Body Mass Index (BMI) in Cystic Fibrosis Patients

Public title
The Efficacy of Compound Honey Syrup in Cystic Fibrosis Patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with cystic fibrosis over 6 years who are able to perform FeNO test.
Exclusion criteria:
Patients with cystic fibrosis under 6 years Patients in need of hospitalization Patients who have exacerbation (increased cough, sputum, fever and need to be hospitalized) Patients with underlying diseases such as allergic bronchopulmonary aspergillosis, heart failure, tuberculosis Patients with another acute illness during treatment Patients who are allergic to any component of the compound honey syrup Patients requesting exclusion Patients unable to perform FeNO test.
Age
From **6 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **40**
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 ملی اخلاق در پژوهش های زیست پزشکی
Street address
Evin, Shahid Shahriari Square
City
Tehran
Province
Tehran
Postal code
1983969411
Approval date
2020-01-18, 1398/10/28
Ethics committee reference number
IR.SBMU.MSP.REC.1398.877

Health conditions studied

1

Description of health condition studied
Cystic Fibrosis
ICD-10 code
ICD-10 code description
ICD-10

Primary outcomes

1

Description
FeNO
Timepoint
At the beginning of the study and 12 weeks after the administration of the compound honey syrup
Method of measurement
FeNO Testing Device

2

Description
Body Mass Index
Timepoint
At the beginning of the study and 12 weeks after the administration of the compound honey syrup
Method of measurement
Weight / Squared Height

3

Description
Pulmonary Symptoms
Timepoint
At the beginning of the study and 12 weeks after the administration of the compound honey syrup
Method of measurement
CFQ-R questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Includes patients with cystic fibrosis over 6 years of age referred to the pulmonary clinic of Mofid Children's Hospital who are able to perform FeNO test.Lung examination for pulmonary symptoms and FeNO test performed by standing pulmonary fellowship, patient's BMI is measured.In the next stage, all standard and required treatments of the patient are prescribed, and in addition to routine treatments, compound honey syrup is also prescribed.Consumption of compound honey syrup is 5-10 cc (depending on the weight of children, 10 cc over 30 kg and 5 cc under 30 kg) in 100 cc of boiled water twice a day 30 minutes after a meal.Compound honey syrup is produced by NIAK Pharmaceutical Company with the permission of the Food and Drug Administration of the Ministry of Health and Medical Education. This syrup contains compounds of honey, cinnamon, ginger, saffron and cardamom .The patient was followed up by the researcher in the second and fourth weeks after the first visit and in the sixth week, the patient referred again to the pulmonary clinic of Mofid Children's Hospital for examination by a pulmonologist and then in the eighth and tenth weeks followed by the researcher by phone, and finally in the twelfth week for the final visit to be examined by a pulmonologist, FeNO test and CFQ-R questionnaire in terms of Pulmonary symptoms are also complemented.

Category

Treatment - Drugs

2

Description

Control group: Includes patients with cystic fibrosis over 6 years of age referred to the Pulmonary Clinic of Mofid Children's Hospital who are able to perform FeNO testing. The patient is examined by the pulmonary fellowship for pulmonary symptoms and BMI, and each patient's information is entered into a CFQ-R questionnaire. In other words, information is collected for each patient before starting treatment with honey syrup.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid children hospital

Full name of responsible person

Nafise Fadavi

Street address

Shariati street

City

Tehran

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

دکتر افشین زرقی

Street address

Shahid Beheshti University of Medical Sciences, Tehran, Iran

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Province

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1985717443

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Fax

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Email

info@sbmu.ac.ir

Web page address

http://sbmu.ac.ir

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
Nafise Fadavi

Position
Ped pulmonology fellow

Latest degree
Specialist

Other areas of specialty/work
Pediatrics

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Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available