

# 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

##### Province

Tehran

##### Postal code

15468-15514

##### Phone

+98 21 2222 7021

##### Fax

+98 21 2222 7021

##### Email

info-mch@sbmu.ac.ir

##### Web page address

http://mch.sbmu.ac.ir

## 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 23871

##### Fax

+98 21 23871

##### 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

**Street address**

No. 5, Yas building, Mobarezan Ave, Bozorgmehr street

**City**

Ardestan

**Province**

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**Postal code**

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**Fax****Email**

nf.fadavi@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Nafise Fadavi

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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