

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2221 4811

##### Email address

dr.hmohammadi@sbm.ac.ir

##### 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

**Street address**

خیابان یمن، دانشگاه علوم پزشکی شهید بهشتی

**City**

تهران

**Province**

Tehran

**Postal code**

1985717443

**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)<sup>2</sup>

### 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**

Hanieh Tahermohammadi

##### **Street address**

Tehran

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1516745811

##### **Phone**

+98 21 8877 3521

##### **Email**

dr.hmohammadi@sbmu.ac.ir

## **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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##### **Email**

dr.hmohammadi@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**

Hanieh Tahermohammadi

**Position**

Assistant of Traditional Medicine

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Faculty of Traditional Medicine, Shams Alley, Tavanir Station, Valiasr St., Tehran Town

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**Phone**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Shahpar Kaveh Bagh Bahadorani

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

hanieh Tahermohammadi

**Position**

Assistant of Traditional Medicine

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

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**Email**

dr.hmohammadi@sbmu.ac.ir

**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**