

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### The efficacy of inhaled formoterol on symptom improvement in covid 19 patients

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of inhaled formoterol to improve respiratory symptoms of COVID 19 patients.

##### Design

The randomized clinical trial with two parallel groups; without blinding, in which 200 patients will be enrolled between 18 April 2020 till 19 June 2020

##### Settings and conduct

200 eligible patients will be divided into two groups by simple randomization. Patients in the Formoterol group will receive one dose of inhaled formoterol twice daily for 10 days along with the national protocol for COVID-19. Disease duration, the mortality rate, and the rate of symptom improvement at the 5th and 10th day based on Complete improvement, Partial improvement, lack of improvement and admission, will be assessed for 30 days.

##### Participants/Inclusion and exclusion criteria

-Patients aged 18 to 75 years old -Both Sexes -COVID-19 patients based on clinical manifestations or according to CBC, CRP, and Chest radiography or other lab tests - patients who voluntarily agree to participate in the study after being fully informed about it and sign the consent form. In the case of Pregnancy, Comorbidity, Saturation less than 93% or any criteria for hospitalization, History of formoterol intolerance, Cardiac diseases, such as heart failure or arrhythmia, Recent history of using inhaled corticosteroids, bronchodilators, and ACE inhibitors, Asthma or a history of Chronic obstructive pulmonary disease (COPD), Heavy smoking, the patient will be excluded.

##### Intervention groups

1- Inhaled Formoterol In this group along with the national regimen according to the national guideline of treatment for COVID-19, patients will take Formoterol (made by Medochemie ) one Puff every 12 hours, for 10 days. 2- Control group: receive national regimen for COVID-19 according to national protocol.

##### Main outcome variables

five-day symptom improvement; 10-day symptom improvement; Total time since randomization until clinical improvement.

#### General information

##### Reason for update

For the title, respiratory symptoms were considered, thus, the title was revised. During the Implementation of the trial, exclusion criteria were expanded; so, this part of the protocol was amended. Some exclusion criteria such as asthma and cardiac disease were added. The sample size was increased to have more similarity in baseline characteristics in treatment and control groups. In each arm. 100 participants were considered. The trial was multicenter, so all recruit centers were added.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170210032478N3**  
Registration date: **2020-04-29, 1399/02/10**  
Registration timing: **registered\_while\_recruiting**

Last update: **2021-01-02, 1399/10/13**

Update count: **1**

##### Registration date

2020-04-29, 1399/02/10

##### Registrant information

###### Name

**Name of organization / entity**

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2712 2163

###### Email address

dr.f.ghorbani@sbsmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2020-04-18, 1399/01/30

**Expected recruitment end date**

2020-06-19, 1399/03/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The efficacy of inhaled formoterol on symptom improvement in covid 19 patients

**Public title**

Effect of Formoterol in treatment of covid19

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

(COVID-19) with according to the clinical manifestations confirmed with CBC, CRP, and Chest radiography or other lab tests Patients who voluntarily sign our consent form.

**Exclusion criteria:**

Pregnancy Comorbidity Saturation less than 93% The presence of symptoms for more than 7 days History of formoterol intolerance cardiac diseases, such as heart failure or arrhythmia Recent history of using inhaled corticosteroids, bronchodilators, and ACE inhibitors Asthma or COPD Heavy Smoker

**Age**From **18 years** old to **75 years** old**Gender**

Both

**Phase**

3

**Groups that have been masked***No information***Sample size**Target sample size: **200****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using even and odd numbers, the patients are simply randomized and placed in two groups of intervention and (no- intervention).

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of National Research Institute of Tuberculosis and Lung Diseases

**Street address**

Niavaran, Daaraabaad

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Tehran

**Province**

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**Postal code**

1956744413

**Approval date**

2020-03-10, 1398/12/20

**Ethics committee reference number**

IR.SBMU.NRITLD.REC.1399.003

**Health conditions studied****1****Description of health condition studied**

corona virus or COVID-19

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19, virus identified

**2****Description of health condition studied**

COVID 19 ,virus not identified

**ICD-10 code**

U07.2

**ICD-10 code description**

COVID-19, virus not identified

**Primary outcomes****1****Description**

Level of Improvement

**Timepoint**

the 5th and 10th days

**Method of measurement**

clinical evaluation, observation, physical examination, and call interview for follow up

**Secondary outcomes****1****Description**

Total time to improvement

**Timepoint**

up to 30 days follow-up

**Method of measurement**

observation

**Intervention groups****1****Description**

Intervention group: Inhaled Formoterol. In this group along with the standard regiment according to the national guideline of treatment for COVID-19, patients will take Formoterol 1 Puff every 12 hours made by Medochemie Company for 10 days.

**Category**

Treatment - Drugs

**2****Description**

Control group: standard treatment according to protocol

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Masih Daneshvari Hospital

**Full name of responsible person**

Giti Pourdowlat

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No. 1, Masih Daneshvari Hospital, Daraabaad, Niavaran

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**Web page address****2****Recruitment center****Name of recruitment center**

Qum

**Full name of responsible person**

Abolfazl Mozafari

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Islamic Azad University of Qom , 15-Khordad hospital,

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**Web page address****3****Recruitment center****Name of recruitment center**

Razi Hospital

**Full name of responsible person**

Azita Tangestani Nejad

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**Web page address****4****Recruitment center****Name of recruitment center**

Semnan University of medical sciences

**Full name of responsible person**

Mahboobeh Darban

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Bassij Blvd, Headquarter of Semnan University of Medical Sciences and Health Services

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Dr.mdarban@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

National Research Institute of Tuberculosis and Lung Diseases

**Full name of responsible person**

Dr. Parisa Farnia

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No 1, Masih Daneshvari Hospital, Daaraabaad,

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tdrc.nritld@yahoo.com  
**Web page address**  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
National Research Institute of Tuberculosis and Lung Diseases  
**Proportion provided by this source**  
50  
**Public or private sector**  
Private  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## 2

### **Sponsor**

**Name of organization / entity**  
Medochemie KSN  
**Full name of responsible person**  
Farzaneh Rahatlou  
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No. 30, Dameshgh Street, Valiasr Street,  
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**Phone**  
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rahatlou@nikanmedicalgroup.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Medochemie KSN  
**Proportion provided by this source**  
50  
**Public or private sector**  
Private  
**Domestic or foreign origin**

Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Industry

### **Person responsible for general inquiries**

#### **Contact**

**Name of organization / entity**  
National Research Institute of Tuberculosis and Lung Diseases  
**Full name of responsible person**  
Fariba Ghorbani  
**Position**  
Consultant  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Biotechnology  
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### **Person responsible for scientific inquiries**

#### **Contact**

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National Research Institute of Tuberculosis and Lung Diseases  
**Full name of responsible person**  
Guitti Pourdowlat  
**Position**  
Assistant Proffessore  
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## Person responsible for updating data

### Contact

**Name of organization / entity**

National Research Institute of Tuberculosis and Lung Diseases

**Full name of responsible person**

Fariba Ghorbani

**Position**

Researcher

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Tissue Engineering

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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**

Not applicable

**Data Dictionary**

Not applicable