

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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@sbm.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

AgeFrom **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

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Niavaran, Daaraabaad

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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 Pourdoulat

Street address

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

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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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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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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
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Other areas of specialty/work
Medical Biotechnology
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Person responsible for scientific inquiries

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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