Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 regiment 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@sbmu.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
City
Tehran
Province
Tehran
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
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2712 2163
Fax
+98 21 2610 5387
Email
pourdowlat_g@yahoo.com
Web page address

2

Recruitment center
Name of recruitment center
Qum
Full name of responsible person
Abolfazl Mozafari
Street address
Islamic Azad University of Qom , 15-Khordad hospital,
City
Qum
Province
Tehran
Postal code
3749113191
Phone
+98 25 3280 7070
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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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Razi Medical Cente, Sardar Jangal St.
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Rasht
Province
Guilan
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41448
Phone
+98 31 3355 0028
Email
aznejad@yahoo.com
Web page address

4

Recruitment center
Name of recruitment center
Semnan University of medical sciences
Full name of responsible person
Mahboobeh Darban
Street address
Bassij Blvd, Headquarter of Semnan University of Medical Sciences and Health Services
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Markazi
Postal code
35147-99442
Phone
+98 23 3345 2199
Email
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
Street address
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

Street address
No. 30, Dameshgh Street, Valiasr Street,

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Province
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1416743147

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Email
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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No. 1,Daraabaad Ave., Niavaran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
National Research Institute of Tuberculosis and Lung Diseases

Full name of responsible person
Guitti Pourdowlat

Position
Assistant Proffessore

Latest degree
Subspecialist

Other areas of specialty/work
Pulmonologyst

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Email
pourdowlat_g@yahoo.com

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