

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Effects of colchicine on persistent dyspnea and pulmonary fibrosis of COVID-19 patients after hospital discharge

Protocol summary

Study aim

Effects of colchicine on persistent dyspnea and pulmonary fibrosis of COVID-19 patients after hospital discharge

Design

40 patients with history of persistent dyspnea after COVID19 infection are divided into two groups. 20 patients receiving colchicine and the other 20 receiving placebo to compare effect of colchicine on persistent dyspnea and pulmonary fibrosis sampling: sampling was non randomized convenience sampling double blinded clinical trial phase 2

Settings and conduct

COVID19 patients 2 months after discharging from hospital were assessed by an internist based on UCSD form for dyspnea and lung CT scan .patients with persistent dyspnea and/ or pulmonary fibrosis were enrolled in control (placebo)and treatment(colchicine) group randomly .patients and investigators were blinded .a reassessment was done after 1 and then 6 month

Participants/Inclusion and exclusion criteria

inclusion criteria: history of COVID19 infection confirmed with CT scan or/and positive PCR exclusion criteria: history of taking colchicine. pregnancy. history of allergic reaction to colchicine. taking immunosuppressant drugs. history of chronic dyspnea. non consent

Intervention groups

40 patients with history of COVID19 infection are divided into two groups. 20 patients receiving colchicine and the other 20 receiving placebo to compare effect of colchicine on persistent dyspnea

Main outcome variables

persistent dyspnea and/ or pulmonary fibrosis in COVID-19 patients at least 2 month after discharge from hospital and clinical effects of colchicine in treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200707048047N1**
Registration date: **2021-03-27, 1400/01/07**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-27, 1400/01/07**

Update count: **0**

Registration date

2021-03-27, 1400/01/07

Registrant information

Name

Masoumeh Moallem

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2611 6628

Email address

masoumehmoallem@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of colchicine on persistent dyspnea and pulmonary fibrosis of COVID-19 patients after hospital discharge

Public title

colchicine effect on persistent dyspnea in COVID19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

history of covid19 infection confirmed with lung lesion in CT scan and/or positive PCR

Exclusion criteria:

history of taking colchicine..history of ipf.non consent pregnancy history of allergic reaction to colchicine immunosuppressive drug consumption history of chronic dyspnea or dyspnea on exertion due to underlying diseases non consent in any stage of study

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

in this study both control and treatment group receive supportive treatment. drug and placebo are packed in packages and are blindly distributed between patients.principle investigators and health care providers were blinded in this study

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Islamic Azad Tehran Medical Sciences University - Pharmacy and Pharmaceutical Branches Faculty

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Postal code

1916893813

Approval date

2021-01-31, 1399/11/12

Ethics committee reference number

IR.IAU.PS.REC.1399.255

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

COVID19

ICD-10 code

U07.1

ICD-10 code description

U07.1

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

UCSD نمره تنگی نفس بر اساس پرسش نامه

Timepoint

Before intervention,1and6months after intervention

Method of measurement

UCSD questionnaire

Secondary outcomes

empty

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

Intervention group: patients with history of Covid19 infection with persistent dyspnea and pulmonary fibrosis receive colchicine 0.5mg BID for 3 days and then 0.5 mg daily for 1 month

Category

Treatment - Drugs

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

Boali hospital Tehran

Full name of responsible person

Masoumeh moallem

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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

Islamic Azad University

Proportion provided by this source

20

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

Islamic Azad University

Full name of responsible person

masoumeh moallem

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Contact

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Person responsible for updating data

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Latest degree

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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