Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 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 onpersistent 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
Street address
خاقانی
City
tehran
Province
Tehran
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
نمره تنگی نفس بر اساس پرسش نامه UCSD
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
Street address
Boali hospital,Damavand st,Imam Hosein sq,Tehran
City
Tehran
Province
Tehran
Postal code

1711734365
Phone
+98 21 3334 8036
Email
masoumehmoallem@gmail.com
Web page address
http://bouali.iautmu.ac.ir/fa

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Alireza Khoshdel
Street address
khaghani
City
Tehran
Province
Tehran
Postal code
1916893813
Phone
+98 21 2200 6660
Email
pezeshkitehran.8@gmail.com
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
Emergency Medicine
Street address
Dastgerdi
City
Tehran
Province
Tehran
Postal code
1918613511
Phone
+98 21 2222 3567
Email
masoumehmoallem@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Shimaa Mosalanejad
Position
assistant professor
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Khaje abdollah
City
tehran
Province
Tehran
Postal code
1661645320
Phone
+98 21 2232 2780
Email
shimaamosalanejad@gmail.com

Person responsible for updating data

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
Emergency Medicine
Street address
Tehran
City
Tehran
Province
Tehran
Postal code
1918613511
Phone
+98 21 2222 3567

Email
masoumehmoallem@gmail.com

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