Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Investigation of the efficacy and safety of colchicine In combination with standard treatment on covid-19 patients: A clinical trial

Protocol summary

Study aim
Evaluation of the efficacy and safety of colchicine in combination with standard treatment in patients with covid 19

Design
Clinical trial with control group, with parallel, double blind and randomized groups

Settings and conduct
This is a prospective, double-blind, randomized controlled clinical trial, and the patient, physician and evaluator will be unware of all steps

Participants/Inclusion and exclusion criteria
Entry:Age 18 to 70 years; Detection of COVID-19 in the last 24 to 48 hours; o2sat <93% or RR> 24 or Pao2 / Fio2 <300; Covid-19 patients hospitalized with hospital indications according to the guideline of the country that has pulmonary infiltration in CT scan; No consumption colchicine during the last week ;Exclusion: Patients with a history of chronic Crohn's or colitis, diarrhea, or chronic malabsorption; History of cirrhosis, hepatitis and severe liver disease; Patients currently taking colchicine for other uses, such as gout or Mediterranean fever; Patients with a history of allergic reactions or allergies to colchicine; Patients receiving chemotherapy for cancer

Intervention groups
Patients in the Colchicine group take half a milligram a day for one to three days, and one milligram a day for the next 12 days in addition to standard treatment, patients in the control group take standard treatment

Main outcome variables
clinical symptoms including fever, cough, shortness of breath;laboratory symptoms (ESR, CRP, NLR, LDH, ferritin, D-dimer, CBC diff); o2sat at the time of hospitalization and discharge; finding of pulmonary infiltration in CT scan

General information

Reason for update
Registration of the second center according to the nationality of the project Remove the placebo

Acronym

IRCT registration information
IRCT registration number: **IRCT20190810044500N5**
Registration date: **2020-05-18, 1399/02/29**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-12, 1400/01/23**
Update count: **1**

Registration date
2020-05-18, 1399/02/29

Registrant information

Name
Fatemeh Saghafi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-04, 1399/01/16

Expected recruitment end date
2021-02-04, 1399/11/16

Actual recruitment start date
2020-03-26, 1399/01/07

Actual recruitment end date
2020-12-30, 1399/10/10

Trial completion date
2021-01-14, 1399/10/25

Scientific title
Investigation of the efficacy and safety of colchicine In

combination with standard treatment on covid-19 patients: A clinical trial

Public title
Effect of colchicine in treatment of COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
- Age 18 to 70 years - Detection of COVID-19 in the last 24 to 48 hours - Candidate for hospitalization (o2sat <93% or RR> 24 or Pao2 / Fio2 <300) - COVID-19 patients hospitalized with hospital indications according to the guideline of the country that has pulmonary infiltration in CT scan -Not being pregnant and not becoming pregnant until 30 days after the end of the study - No consumption of colchicine during the last week (due to the half-life of 20-40 hours of the drug) - Outpatients with pulmonary infiltration on CT scan
Exclusion criteria:
Patients with a history of Crohn or Ulcerative colitis, diarrhea, or chronic malabsorption Neuromuscular diseases GFR less than 30 ml per minute History of cirrhosis, hepatitis and severe liver disease Patients receiving chemotherapy for cancer Patients currently taking colchicine for other uses, such as gout or Mediterranean fever Patients with a history of allergic reactions or allergies to colchicine Pregnancy and lactation
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **200**
Actual sample size reached: **152**
Randomization (investigator's opinion)
Randomized
Randomization description
At the beginning of the study, patients will be assigned to one of the two divided groups with a random number table
Blinding (investigator's opinion)
Double blinded
Blinding description
All stages will be covered by the patient, the treating physician and the evaluators. In this way, the first executor of the sequence plan specifies the allocation of people according to the order of admission of sick people to the study and pours the drugs into one-packets for consumption for two weeks and identifies them with A or B codes. Then, the drugs suitable for each person are identified according to the above explanations and placed in special envelopes and delivered to patients. One group is given a placebo and standard treatment and the other group is given a colchicine and standard treatment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Committee for Ethics in Biomedical Research
Street address
Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran
City
tehran
Province
Tehran
Postal code
8915173143
Approval date
2020-04-02, 1399/01/14
Ethics committee reference number
IR.SBMU.NRITLD.REC.1399.018

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19,virus identified

Primary outcomes

1

Description
-Clinical symptoms including fever, cough, shortness of breath
Timepoint
The first, third, seventh, fourteenth and 6-8 days after entering the study
Method of measurement
questionnaire

2

Description
pulmonary infiltration findings on CT scan
Timepoint
Two weeks later and 6-8 weeks later
Method of measurement

CT-scan

3

Description
o2sat at the time of hospitalization and discharge
Timepoint
The first, third, seventh, fourteenth and 6-8 days after entering the study
Method of measurement
Pulse Oximeter

4

Description
Laboratory symptoms (ESR, CRP, NLR, LDH, ferritin, D-dimer, CBC diff)
Timepoint
Hospitalization time and discharge time
Method of measurement
Blood test

Secondary outcomes

1

Description
Need hospitalization in icu
Timepoint
The first, third, seventh, fourteenth and 6-8 days after entering the study
Method of measurement
questionnaire

2

Description
Mortality
Timepoint
The first, third, seventh, fourteenth and 6-8 days after entering the study
Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group: Receive 0.5 mg of colchicine until the third day and 12 days later one mg plus standard treatment including 200 mg hydroxychloroquine daily
Category
Treatment - Drugs

2

Description
Control group: From the first to the third day, two tablets of placebo and for the next 12 days, one daily dose in addition to the standard treatment (200 mg hydroxychloroquine daily).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoghi Hospital
Full name of responsible person
Nadia Soltani gerdefaramarzi
Street address
Yazd, Shahid Ghandi Blvd., Ibn Sina St., Shahid Sadoughi Hospital
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https://web.ssu.ac.ir/index.aspx?lang=1&sub=16

2

Recruitment center
Name of recruitment center
NRITLD. Masih daneshvari hospital
Full name of responsible person
Guitti Pourdowlat
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Masoud Mirzaei
Street address
Bahonar Square, the central building of Yazd University of Medical Sciences
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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
Yazd University of Medical Sciences

Proportion provided by this source
100

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
Yazd University of Medical Sciences

Full name of responsible person
Nadia Soltani Gerdefaramarzi

Position
University student

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
Assistant Professor

Latest degree
Ph.D.

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Person responsible for updating data

Contact

Name of organization / entity
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University student

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A Level or less

Other areas of specialty/work
Medical Pharmacy

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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