

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Evaluation of the Pentoxifylline and Colchicine Effectiveness on Clinical Outcome of Hospitalized Patients With moderate to Severe Covid-19 Infection

Protocol summary

Study aim

Evaluation of the Pentoxifylline and Colchicine Effectiveness on Clinical Outcome of Patients with Covid-19 Infection

Design

Clinical trial with control group, with parallel, randomized, phase 3 groups per 100 patients. Excel software rand function was used for randomization.

Settings and conduct

Patients over 40 years of age with moderate to severe severity of covid19 patients admitted to Shafa Hospital in Khorramabad in the year 1400 eligible for inclusion in the study are randomly divided into two groups of intervention and control and their clinical consequences will be examined.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hospitalized patients suspected to Covid19 infection who tested positive for PCR or despite the negative PCR test who have a strong clinical evidence plus typical radiographic sing of Covid19 that is difficult to justify their symptoms based on other diseases. Exclusion criteria: Active peptic ulcer Pregnancy and lactation History of colchicine or pentoxifylline allergy Concomitant use of protease inhibitors, strong inhibitors or inducers of CYP3A4 or pgp drugs, statin other than rosuvastatin Occurrence of side effects Fauvism History of alcohol use Retinopathy Neuromuscular disease Severe renal and hepatic failure Active bleeding ihemorrhage Chronic diarrhea or malabsorption History of heart disease Dissatisfaction with the company

Intervention groups

The intervention group received a 0.5 mg daily of colchicine and 400 mg Pentoxifylline every 12 hours in addition to the standard treatment regimen The control group receiving standard treatment regimen

Main outcome variables

Duration of hospitalization Survival rate of 28 days from the time of hospitalization The duration of recovery or the duration of entry into the disease stage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200721048159N3**

Registration date: **2021-06-03, 1400/03/13**

Registration timing: **prospective**

Last update: **2021-06-03, 1400/03/13**

Update count: **0**

Registration date

2021-06-03, 1400/03/13

Registrant information

Name

Forouzan Ahmadpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3312 0239

Email address

ahmadpoor.f@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-21, 1400/03/31

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Pentoxifylline and Colchicine Effectiveness on Clinical Outcome of Hospitalized Patients With moderate to Severe Covid-19 Infection

Public title

The Effectiveness of Pentoxifylline and Colchicine in the Treatment of Covid-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Hospitalized patients suspected to Covid19 infection SpO2 less than 93% The presence of respiratory symptoms (including shortness of breath, pain and pressure in the chest) older than 40 years

Exclusion criteria:

Active peptic ulcer Pregnancy and lactation History of colchicine or pentoxifylline allergy Concomitant use of protease inhibitors, strong inhibitors or inducers of CYP3A4 or pgg drugs, statin other than rosuvastatin Occurrence of side effects Fauvism History of alcohol use Retinopathy Neuromuscular disease Severe renal failure and GFR less than 30 ml/min Severe hepatic impairment (bilirubin higher than 2 mg/dL and albumin less than 2.8 g/dL) Active bleeding including intracerebral hemorrhage or retinal hemorrhage Chronic diarrhea or malabsorption History of heart disease (heart failure, ventricular arrhythmia, right or left heart block, QTc more than 480 milliseconds) Dissatisfaction with the company

Age

From **40 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the 4-layer randomized block method is used to randomly assign patients to two groups A (pentoxifylline and colchicine) and group B (control group). To do this, first by considering the classes as the age range (65-40) and over 65 years within each class, a list of blocks is written and numbers are assigned to them. (AABB (1) - ABAB (2) -ABBA (3) -BBAA (4) - BABA (5) - BAAB (6)). Then, using a table of random numbers, the numbers between one to 6 (for example, 1,4,5, etc.) are randomly selected, and finally the list of treatment assignments will be formed based on a sequence of letters A and B.

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 Lorestan University of Medical Sciences

Street address

Lorestan, Khorramabad, 3 km of Khorramabad Road, Tehran, Pardis University Complex, Vice Chancellor for Research and Technology, Lorestan University of Medical Sciences, Office of Research Ethics Committee

City

Khorramabad

Province

Lorestan

Postal code

381351698

Approval date

2021-03-10, 1399/12/20

Ethics committee reference number

IR.LUMS.REC.1399.362

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**

Duration of hospitalization

Timepoint

7 -14 days

Method of measurement

Based on patient file information

Secondary outcomes

1

Description

The duration of recovery or the duration of entry into the disease stage

Timepoint

7-14 days

Method of measurement

Based on patient file information

2

Description

Survival rate of 28 days from the time of hospitalization

Timepoint

28 days after starting the study

Method of measurement

Interview with the patient or her family

3

Description

the amount of arterial oxygen saturation

Timepoint

Daily

Method of measurement

Using a device to measure the percentage of oxygen saturation

4

Description

Frequency of transfer to intensive care unit

Timepoint

Daily

Method of measurement

Under supervision

Intervention groups

1

Description

Intervention group: Pentoxifylline group receiving 400 mg every 12 hours (Amin Pharmaceutical Company) plus colchicine half a mg every day (Mofid Pharma Pharmaceutical Company) orally in addition to the standard treatment regimen according to the national protocol (Ramsavir and corticosteroids) For 7-14 days depending on the patient's clinical condition

Category

Treatment - Drugs

2

Description

Control group: Standard treatment regimen according to the national protocol

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital

Full name of responsible person

Forouzan Ahmadpour

Street address

Lorestan, Khorramabad, Piroozi St., Shafa Hospital

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info@shafahospital.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of Lorestan University of Medical Sciences

Full name of responsible person

Ebrahim Falahi

Street address

Lorestan, Khorramabad, Kamalvand, km 4 of Khorramabad road

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falahi.e@lums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research and Technology of Lorestan 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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Khoram-Abad University of Medical Sciences

Full name of responsible person

Forouzan Ahmadpour

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Position

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Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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City

Khorramabad

Province

Lorestan

Postal code**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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable