Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Evaluation of the effects of Pentoxifylline in improving the condition of patients with Covid-19

Protocol summary

Study aim

The aim of this study was to investigate the effects of Pentoxifylline in improving the condition of patients with Covid-19 including saturation of arterial oxygen.

Design

Phase 3 clinical trial, randomized, single blinded with parallel groups on 130 patients

Settings and conduct

Patients referred to Imam Ali Hospital in Alborz, Iran, first performed CT-scan of the chest and then RT-PCR test. Immediately after CT-Scan and Covid-19 clinical diagnosis, patients were divided into intervention and control groups. Patients were monitored for arterial oxygen saturation during hospitalization. The average follow-up time for patients was 10 days.

Participants/Inclusion and exclusion criteria

Inclusion criteria icluded clinical signs of fever (above 38.3 C), dyspnea and cough, and Covid-19 diagnosis based on RT-PCR. Exclusion criteria included diabetes, chronic cardiovascular disease, obesity (with a BMI above 30 kg/m2), cancer, chronic kidney disease, and end-stage kidney disease with hemodialysis.

Intervention groups

Intervention group: Pentoxifylline with a dose of 400 mg, made by Farabi Iran Pharmaceutical Company, was prescribed to patients weighing less than 70 kg every 12 hours and to patients weighing more than 70 kg every 8 hours. This group receives only Pentoxifylline for two days from the hospitalization day. Control group: Vitamin D3 (oral capsule) with a dose of 50,000 units, one capsule at hospitalization day, hydroxychloroquine tablets with a dose of 200 mg every 12 hours for two days from the hospitalization day, serum therapy (2.5 to 3.5 liters) and Nasal Prong was prescribed two to eight liters (based on the patient's dyspnea condition).

Main outcome variables

arterial oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200705048013N1**
Registration date: **2020-07-19, 1399/04/29**
Registration timing: **retrospective**

Last update: **2020-07-19, 1399/04/29**
Update count: **0**

Registration date

2020-07-19, 1399/04/29

Registrant information

Name

Davood Mohammadshahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3255 8920

Email address

d.shahi@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-07-20, 1399/04/30

Actual recruitment start date

2020-02-20, 1398/12/01

Actual recruitment end date

2020-06-19, 1399/03/30

Trial completion date

2020-07-05, 1399/04/15

Scientific title

Evaluation of the effects of Pentoxifylline in improving the condition of patients with Covid-19

Public title
The effect of Pentoxifylline in patients with Covid-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Clinical signs of fever (above 38.3 °C), dyspnea and cough Definite diagnosis of of Covid-19 based on RT-PCR
Exclusion criteria:
Diabetes Chronic cardiovascular disease Obesity (with BMI higher than 30 kg/m2) Cancer Chronic kidney disease End-stage renal disease with hemodialysis
Age
From **30 years** old
Gender
Both

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **150**
Actual sample size reached: **130**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were divided into intervention and control groups based on the last digit of the National ID number based on even and odd numbers, respectively. The zero was also considered even.
Blinding (investigator's opinion)
Single blinded
Blinding description
The control and intervention group entered the statistical analysis software in coded form and only the researcher and clinical caregiver will be aware of the study groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Alborz University of Medical Sciences
Street address
Faculty of medicine, Hassan Abad Ave.
City
Karaj
Province
Alborz
Postal code
3149779453
Approval date
2020-05-30, 1399/03/10
Ethics committee reference number
IR.ABZUMS.REC.1399.102

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
Oxygen saturation of arterial blood
Timepoint
Before intervention, daily after intervention
Method of measurement
Pulse-oximeter monitoring

Secondary outcomes

1

Description
Mortality
Timepoint
7, 14, 21 and 28 days after intervention
Method of measurement
Clinical examination by physician and confirmation of death

2

Description
Refer to the intensive care unit
Timepoint
7, 14, 21 and 28 days after intervention
Method of measurement
Clinical Frailty Scale

Intervention groups

1

Description
Intervention group: Pentoxifylline with a dose of 400 mg, made by Farabi Pharmaceutical Company, Iran, was prescribed to patients weighing less than 70 kg every 12 hours and to patients weighing more than 70 kg every 8

hours. This group receives only Pentoxifylline for two days from the hospitalization day.

Category

Treatment - Drugs

2

Description

Control group: Vitamin D3 (oral capsule) with a dose of 50,000 units, one capsule at hospitalization day, hydroxychloroquine tablets with a dose of 200 mg every 12 hours for two days from the hospitalization day, serum therapy (2.5 to 3.5 liters) and Nasal Prong two to eight liters (depending on the patient's dyspnea condition) were prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam-Ali hospital

Full name of responsible person

Davood Mohammadshahi

Street address

In front of the Daryani garden, Chalous Ave., Taleghani BLV.

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Postal code

3149779453

Phone

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Email

d.shahi@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Dr. Mohammad Nouri-Sepehr

Street address

Deputy of Research and Technology, Saffarian Alley, 45 meters from Golshahr

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3198764653

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research@abzums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj 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

Oroumia University of Medical Sciences

Full name of responsible person

Sajjad Pourasghary

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Library Unit, ImamReza Hospital, Daneshghah Street, Golgasht Street

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Province

East Azarbaijan

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Davood Mohammadshahi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Sajjad Pourasghary

Position
Medical Student

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Study data is categorized and coded with no identifiable individuals.

When the data will become available and for how long
Access to study data after publication of the result is available in the journal.

To whom data/document is available
Anyone interested in using the data can access the study data.

Under which criteria data/document could be used
Study data can be used for comparison with other results.

From where data/document is obtainable
Refer to the study's scientific or public accountability person for data.

What processes are involved for a request to access data/document
The request will be sent by email to person responsible for scientific or public inquiries.

Comments