Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the efficacy of Pentoxiphyllin in hospitalized diabetic patients with covid19

Protocol summary

Study aim
the effectiveness of pentoxifylline compared to dexamethasone in diabetic patients with covid-19

Design
The double-blind, randomized, controlled trial study conducted on 50 diabetic patients with COVID-19. Randomization will be performed using a table of random numbers. Patients will be randomly assigned to either the pentoxifylline/dexamethasone group or the dexamethasone-only group after obtaining written informed consent.

Settings and conduct
Patients diagnosed with COVID-19 who are hospitalized in two educational hospitals in Yazd (Shahid Rahnamoon and Shahid Sadoughi Hospitals) will be included in the study, provided that they have diabetes.

Participants/Inclusion and exclusion criteria
Patients aged 18 to 70 years with a diagnosis of COVID-19 within the last 24 to 48 hours, and candidates for hospitalization (o2sat <93%, RR> 24, or Pao2/Fio2 <300) are enrolled in the study. Patients undergoing treatment with Kaletra, patients with hemodynamic instability, drug intolerance, a history of Crohn's, chronic diarrhea, neuromuscular diseases, GFR less than 30 ml/min, a history of cirrhosis, hepatitis, or severe liver disease, patients with cancer, and pregnant or lactating patients will be excluded from the study.

Intervention groups
patients are treated with a dosage of 400 mg three times a day, along with intravenous administration of dexamethasone at a dose of 4 mg every 12 hours. In the control group, patients only receive intravenous dexamethasone at a dose of 4 mg every 12 hours. Treatment continues for seven days.

Main outcome variables
The improvement of the general condition of the patients, the levels of inflammatory markers and the level of involvement in the HRCT before the admission of the patients, any possible drug complications, as well as the need for hospitalization in the intensive care unit and the need for intubation, as well as the mortality rate will be recorded.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230523058271N1**
Registration date: **2023-10-08, 1402/07/16**
Registration timing: **retrospective**

Last update: **2023-10-08, 1402/07/16**
Update count: **0**

Registration date
2023-10-08, 1402/07/16

Registrant information

Name
zahra falahati marvast

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3837 4596

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-12, 1401/10/22

Expected recruitment end date
2023-05-05, 1402/02/15

Actual recruitment start date
2023-01-15, 1401/10/25

Actual recruitment end date

2023-05-20, 1402/02/30

Trial completion date

2023-05-20, 1402/02/30

Scientific title

Evaluation of the efficacy of Pentoxiphyllin in hospitalized diabetic patients with covid19

Public title

Evaluation of the efficacy of Pentoxiphyllin in hospitalized diabetic patients with covid19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of covid in the last 24 to 48 hours Candidate for hospitalization (o2sat<93% or RR>24 or Pao2/Fio2<300) Covid-19 patients who are candidates for hospitalization with indications for hospitalization according to the country's guidelines, who had pulmonary infiltration in CT scan Outpatients with pulmonary infiltration on CT scan Age 18 to 70 years

Exclusion criteria:

Patients who were treated with Coltera (lupinavir/ritonavir). Patients with shock or hemodynamic instability Drug intolerance Patients with a history of Crohn's or ulcerative colitis, diarrhea or chronic malabsorption Neuromuscular diseases GFR less than 30 ml/min History of cirrhosis, hepatitis and severe liver diseases Patients receiving chemotherapy for cancer Pregnancy and breastfeeding

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Actual sample size reached: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who meet the inclusion criteria are divided into two groups by a simple randomization method and based on the table of random numbers prepared by the statistics consultant whom out of the study, and the grouping of each person is in a sealed envelope at the disposal of the relevant doctor and the nursing team. will be placed

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, the researcher and the statistical analyst will not know about the grouping. In this way, only the doctor who prescribed the patient's orders, the nursing team and the patient knew about the medicine received, and the researcher who was responsible for collecting the information and results of the patients would not know about the grouping, and the statistical researcher would also know that each of It will not be known what drugs the groups received.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Shahid Sadoughi University of Medical Sciences, Shohday gomnam Boulevard, Alam Square, Yazd, Iran

City

yazd

Province

Yazd

Postal code

8916978477

Approval date

2023-01-11, 1401/10/21

Ethics committee reference number

IR.SSU.MEDICINE.REC.1401.198

Health conditions studied

1

Description of health condition studied

covid 19

ICD-10 code

Post-COVID

ICD-10 code description

U09

Primary outcomes

1

Description

recovery

Timepoint

It is evaluated during the first 72 hours after hospitalization and the start of the intervention.

Method of measurement

It is evaluated in the form of arterial blood oxygen level of at least 93%, cessation of fever for 72 hours and improvement of the general condition through a questionnaire.

2

Description
IL-6
Timepoint
At the start of treatment and after one week from the start of treatment
Method of measurement
kit

3

Description
CRP
Timepoint
At the start of treatment and after one week from the start of treatment
Method of measurement
kit

4

Description
ESR
Timepoint
At the start of treatment and after one week from the start of treatment
Method of measurement
KIT

5

Description
ferritin
Timepoint
At the start of treatment and after one week from the start of treatment
Method of measurement
kit

6

Description
Involvement in HRCT
Timepoint
At the start of treatment and after one week from the start of treatment
Method of measurement
Using CT SCAN observation and evaluation by a lung specialist

7

Description
Hospitalization in ICU
Timepoint
During the course of treatment
Method of measurement
CHECKLIST

8

Description
death
Timepoint
During the course of treatment
Method of measurement
CHECKLIST

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: They are treated with pentoxifylline 400 mg three times a day along with intravenous dexamethasone 4 mg every 12 hours.
Category
Treatment - Drugs

2

Description
Control group: They are treated with intravenous dexamethasone 4 mg every 12 hours.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadouqi Hospital
Full name of responsible person
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Shahid Sadoughi University of Medical Sciences, Shohday gomnam Boulevard, Alam Square, Yazd, Iran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Research Vice President of 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
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Position
Pharmacy student
Latest degree
A Level or less
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Person responsible for updating data

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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

Yes - There is 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

Only a part of the data, such as the information related to the main outcome or the like, can be shared.

When the data will become available and for how long

One year after the time of publication

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

The data will be available only to researchers working in academic and scientific institutions

From where data/document is obtainable

The data will only be available to researchers working in academic and scientific institutions through the following email address.

What processes are involved for a request to access data/document

Only the data related to the main results of the study can be presented to the mentioned people after mentioning the valid reason.

Comments