Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Evaluation of pentoxifylline effect in treatment of patients with COVID-19, hospitalized in an intensive care unit, A randomized clinical trial

Protocol summary

Study aim
Evaluation of the effect of pentoxifylline in the treatment of patients with Covid-19 disease admitted to the intensive care unit

Design
A randomized clinical trial with a control group and pararell design of 20 patients

Settings and conduct
This study is performed as a clinical trial in Razi Hospital, Rasht, on critically ill patients with COVID-19 admitted to the intensive care unit. After obtaining the informed consent of the patients or their companions, they will enter the study and will be divided into two groups with a ratio of 1: 1 using the randomization method. The website https://www.sealedenvelope.com will be used for randomization. Participants and health care providers responsible for the patient's health will not be blind. Radiologists, research evaluators, and statisticians will be blind to patients' group therapy. For 14 days, patients will be monitored daily for vital signs, blood tests, chest radiographs, and possible gastrointestinal complications. Finally, the two groups will be compared in terms of treatment effectiveness and possible side effects of treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Patients with a diagnosis of respiratory distress and dyspnea with SPAO2 less than 93% or positive PCR and radiographic test on CT SCANNING or Chest X-Ray admitted to the intensive care unit.
Exclusion criteria: pregnant patients, patients who get under therapy for less than 3 days.

Intervention groups
Treatment group: includes 10 patients who receive the national standard treatment regimen for COVID-19 with pentoxifylline for 14 days.Control group: including 10 patients receiving the standard COVID-19 treatment regimen based on the national protocol for 14 days.

Main outcome variables
Clinical signs of covid-19 disease,recovery rate, possible drug side effects,oxygen saturation percentage.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110425006280N11**
Registration date: **2021-01-27, 1399/11/08**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-27, 1399/11/08**
Update count: **0**

Registration date
2021-01-27, 1399/11/08

Registrant information

Name
Mohammad Haghighi

Name of organization / entity
Guilan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-19, 1399/10/30

Expected recruitment end date
2021-03-20, 1399/12/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of pentoxifylline effect in treatment of patients with COVID-19, hospitalized in an intensive care unit, A randomized clinical trial

Public title
The effect of pentoxifylline in the treatment of Covid-19 disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with a clinical diagnosis of respiratory distress and dyspnea with SPAO2 less than 93% or positive PCR and radiographic test on CT SCANNING or Chest X-Ray admitted to the intensive care unit

Exclusion criteria:
pregnant patients patients who get under therapy for less than 3 days

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
2

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, patients will be randomly admitted to each of the two treatment groups using the randomization method with a ratio of 1:1. 20 patients with Covid-19 disease will be divided into 2 groups of 10 intervention and control. The intervention group will be named A and the control group will be named B. Random blocking will be such that the patients will be assigned numbers 1 to 20, respectively. Then a table will be considered with 6 rows called blocks and each block with 4 parts and each part will be named A and B. In the next step, the numbers will be placed in each cell in order. After all the numbers are placed in the blocks, the people who had the number in house A will receive the intervention medicine and the people who had the number in house B will be considered as the control group. The website https://www.sealedenvelope.com will be used for randomization.

Blinding (investigator's opinion)
Single blinded

Blinding description
Each patient's group therapy will be determined only after randomization. Participants and health care providers responsible for patients' health will not go blind and will be informed about group therapy. Radiologists, research evaluators, and statisticians will be blind to patients' group therapy. The Sequentially numbered opaque, sealed envelopes: Envelopes method is used to hide random allocation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical Comeetee of Guilan University of Medical Sciences

Street address
Namjoo Avenue, Deputy department OF Guilan University of Medical Sciences

City
Rasht

Province
Guilan

Postal code
4193713189

Approval date
2021-01-06, 1399/10/17

Ethics committee reference number
IR.GUMS.REC.1399.458

Health conditions studied

1

Description of health condition studied
The effect of pentoxifylline in the treatment of covid-19 disease

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Clinical signs of COVID-19 disease

Timepoint
Daily in the morning visit for 14 days

Method of measurement
Observe, measure and record fever, cough, shortness of breath, olfactory and taste disorders, headache, gastrointestinal symptoms, chills and ...

2

Description
Percentage of oxygen saturation
Timepoint
Daily in the morning visit for 14 days
Method of measurement
Based on measurements with pulse oximetery

Secondary outcomes

1

Description
Patient`s recovery
Timepoint
Daily in the morning visit for 14 days
Method of measurement
No need for supplemental oxygen or mechanical ventilation and ICU discharge

Intervention groups

1

Description
Intervention group: This study is performed in critically ill patients with COVID-19 admitted to Razi Hospital after obtaining informed consent from the patient or their companions.The 10 eligible patients randomly selected will receive the national standard COVID-19 treatment regimen with pentoxifylline. The current standard treatment includes antiviral drug Remdesivir, a dose of 200 milligrams on the first day and then 100 milligrams for 5 days, which can be extended to 10 days depending on the clinical condition. The next drug is ReciGen, which is an interferon beta-1 drug. It is given to the patient at a dose of 44 micrograms subcutaneously for 5 days (every other day). The next drug is dexamethasone, which is a glucocorticoid and is given to the patient at a dose of 8 milligrams per day for 10 days. Heparin at a dose of 5000 units subcutaneous 3 times a day, pantoprazole at a dose of 40 milligrams once a day and vitamin C one gram twice a day will be considered for patients.The dose of pentoxifylline is 400 milligrams, which is determined based on creatinine clearance of the patient as follows: Creatinine clearance above 50 milliliters per minute: three times a day, creatinine clearance 10 to 50 milliliters per minute: twice a day, Creatinine clearance less than 10 milliliters per minute: once daily. The treatment period for patients is 14 days. For 14 days, they will be monitored daily for vital signs, electrolytes, blood sugar, liver tests, kidney tests, blood cells, coagulation factors, LDH, inflammatory factors, chest radiographs, and possible gastrointestinal complications. Finally, the two groups will be compared in terms of treatment effectiveness and possible side effects of treatment.
Category
Treatment - Drugs

2

Description
Control group: 10 patients receive the standard COVID-19 treatment regimen based on national protocol. The current standard treatment includes antiviral drug Remdesivir, a dose of 200 milligrams on the first day and then 100 milligrams for 5 days, which can be extended to 10 days depending on the clinical condition. The next drug is ReciGen, which is an interferon beta-1 drug. It is given to the patient at a dose of 44 micrograms subcutaneously for 5 days (every other day). The next drug is dexamethasone, which is a glucocorticoid and is given to the patient at a dose of 8 milligrams per day for 10 days. Heparin at a dose of 5000 units subcutaneous 3 times a day, pantoprazole at a dose of 40 milligrams once a day and vitamin C one gram twice a day will be considered for patients.For 14 days, patients are monitored daily for vital signs, electrolytes, blood sugar, liver tests, kidney tests, blood cells, coagulation factors, LDH, inflammatory factors, chest radiographs, and possible gastrointestinal complications. Finally, the two groups are compared in terms of treatment effectiveness and possible side effects of treatment.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Dr Mohammad Haghighi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice President of Research Guilan university of medical sciences
Full name of responsible person
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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
Vice President of Research Guilan 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
Guilan University of Medical Sciences
Full name of responsible person
Mohammad Haghighi
Position
Full professor of Critical Care Medicine
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Person responsible for updating data

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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