

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 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 Haghghi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3211 1319

Email address

mohaghghi@gums.ac.ir

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 SpO₂ 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 Committee 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 oximetry

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 Haghghi

Street address

Razi Hospital, Sardar Jangal Street, Rasht

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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

Dr Mohammadreza Naghipoor

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Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street, Rasht

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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

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Web page addresshttps://isid.research.ac.ir/Mohammad_Haghighi2**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Mohammad Haghighi

Position

Professor of Critical Care Medicine

Latest degree

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Other areas of specialty/work

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Web page addresshttps://isid.research.ac.ir/Mohammad_Haghighi2**Person responsible for updating data****Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

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Position

Research Expert/(MSc) English

Latest degree

Master

Other areas of specialty/work

Expert of Research Affairs

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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