Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

The evaluation of pirfenidone effects on prevention and treatment of pulmonary fibrosis and acute respiratory distress syndrome caused by COVID-19

Protocol summary

Study aim

The effect of pirfenidone on prevention and treatment of pulmonary fibrosis and acute respiratory distress syndrome caused by COVID-19

Design

Randomized clinical trial, with parallel, intervention and control groups, single-blind, simple randomization

Settings and conduct

This is a clinical trial study which will be performed in Golestan and Farabi Hospitals,Kermanshah,Iran. Pirfenidone 200 mg three times daily, along with standard treatment in the intervention group will be administered for 14 days. Individuals at Control group will recieve the standard treatment for the same period.

Participants/Inclusion and exclusion criteria

Inclusion criteria o Confirmed cases of COVID-19 who are 18 years and older; °Not more than 14 days passed from the onset of symptoms o Bilateral lung involvement o Moderate to severe ARDS Exclusion criteria ■ AST and ALT> 3-5x ULN, bilirubin> 1.5 x ULN at visit •Creatinine clearance rate at visit 1 <30 mL / min ■ Previous treatment with nidanib or pirfenidone ■Significant pulmonary hypertension ■Cardiovascular diseases, including: ① Severe hypertension within 6 months of Visit 1, uncontrollable after treatment (≥160 / 100 mmHg); ② myocardial infarction and unstable angina ■History of severe central nervous system events ■Known trial Drug allergies ■Patients unable to follow the trial procedures

Intervention groups

Intervention group: Pirfenidone 200 mg ,TDS along with standard treatment (according to the national protocol of Coltra (Lupinavir / Ritonavir)100/400mg twice daily, chloroquine 250 mg twice daily, and siltamivir 75 mg twice daily in critically ill patients with ribavirin 1200 twice daily.) Patients in the control group will receive standard treatment.

Main outcome variables

Chest CT [Time Frame: 2 weeks]Lesion area of chest CT; Finger pulse oxygen and blood gases[2 weeks]Absolute change in pulse oxygen from baseline; Dyspnea;fever;cough;malaise.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200314046764N1**
Registration date: **2020-04-20, 1399/02/01**
Registration timing: **prospective**

Last update: **2020-04-20, 1399/02/01**
Update count: **0**

Registration date

2020-04-20, 1399/02/01

Registrant information

Name

Bahareh Baghchi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3835 4444

Email address

bahareh.baghchi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-26, 1399/02/07

Expected recruitment end date

2020-05-13, 1399/02/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of pirfenidone effects on prevention and treatment of pulmonary fibrosis and acute respiratory distress syndrome caused by COVID-19

Public title

Pirfenidine in SARS-COV2

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmed cases of New coronavirus infection or COVID-19 who are 18 years and older; Not more than 14 days from the onset of symptoms Bilateral lung involvement in imaging findings Moderate to severe acute respiratory distress syndrome Decreased PaO2 to FiO2 ratio

Exclusion criteria:

AST and ALT> 3-5x ULN at visit and bilirubin> 1.5 x ULN at visit creatinine clearance rate calculated by Cockcroft-Gault formula at visit 1 <30 mL / min Confirmed previous Idiopathic pulmonary fibrosis,previous treatment with Nidanib or Pirfenidone Significant pulmonary hypertension (PAH) Cardiovascular diseases, including any of the following diseases: ① Severe hypertension within 6 months of Visit 1, uncontrollable after treatment (≥160 / 100 mmHg); ② myocardial infarction within 6 months of visit 1; ③ unstable angina within 6 months of visit 1 history of severe central nervous system (CNS) events known trials Drug allergies Patients unable to follow the trial procedures Pregnancy Breastfeeding

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to prevent bias, a simple randomization method will be used in this study to perform random allocation. We will produce 40 cards , completely identical in appearance. "Number 1" will be written on 20 of them indicating the intervention and on the other 20 cards left, we will write "number 2" which indicates the control group. Each eligible participant then randomly picks one of these cards, which determines how the patients will be randomly assigned to each group. Without the trial participants being informed of the nature of either 1 or 2 numbers.

Blinding (investigator's opinion)

Single blinded

Blinding description

I this study the researcher, questionnaire data recorder, the radiologist evaluating imaging findings, outcome assessors, and data analyser are unaware of patients' affiliation to each group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Branch of researchs and industry,Kermanshah University Of Medical Sciences, Shahid Beheshti Blvd, Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2020-03-03, 1398/12/13

Ethics committee reference number

IR.KUMS.REC.1399.017

Health conditions studied

1

Description of health condition studied

Pulmonary fibrosis and acute respiratory distress syndrome caused by novel corona-virus pneumonia (COVID-19)

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

The scales of pulmonary involvement changes according to the scoring system defined, based on high resolution

pulmonary computed tomography before and after the interventions

Timepoint

At visit 1 and then after 14 days.

Method of measurement

Defined scoring system based on pulmonary involvement in high resolution pulmonary CT scan; score one: involvement in less than 5% of a lobe of a lung. Score two: Conflict about 25 percent of a lobe of a lung. Score three: Conflict about 26 to 49 percent of a lobe of a lung. Score four: Conflict about 50 to 75 percent of a lobe of a lung. Score Five: Conflict in more than 75% of a lobe of a lung

Secondary outcomes

1

Description

Changes in arterial gas content

Timepoint

Weekly for 2 weeks

Method of measurement

Paraclinical tests (blood tests)

2

Description

Feeling nauseous

Timepoint

Daily for 14 days

Method of measurement

Through direct questioning of the patient as well as objective observations

3

Description

Shortness of breath

Timepoint

Daily for 14 days

Method of measurement

Through direct questioning of the patient as well as objective observations

4

Description

feeling exhausted

Timepoint

Daily for 14 days

Method of measurement

Through direct questioning of the patient as well as objective observations

5

Description

Shievering

Timepoint

Daily for 14 days

Method of measurement

Through direct questioning of the patient as well as objective observations

6

Description

Cough

Timepoint

Daily for 14 days

Method of measurement

Through direct questioning of the patient as well as objective observations

Intervention groups

1

Description

Intervention group: Pirfenidone 200 mg ,three times daily in addition to standard treatment (according to the national protocol) containing Coltra Lupinavir / Ritonavir twice daily, Chloroquine 250 mg twice daily, and Osiltamivir 75 mg twice daily, in critically ill patients with ribavirin 1200 twice daily.)

Category

Treatment - Drugs

2

Description

Control group: In the control group, standard treatment according to the national protocol containing Coltra (Lupinavir / Ritonavir) 100mg/400mg twice daily, chloroquine 250 mg twice daily, and siltamivir 75 mg twice daily in critically ill patients with ribavirin 1200 twice daily.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital, Kermanshah

Full name of responsible person

Bahareh Baghchi

Street address

Baghabrisham Ave., Parastar Blvd., Medicine school

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Kermanshah

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Email

bahareh.baghchi@kums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Farid Najafi
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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
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Bahareh Baghchi
Position
Assistant Professor of emergency medicine
Latest degree
Specialist
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Person responsible for updating data

Contact
Name of organization / entity
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Mohammad Nazarian Pirdoosti
Position
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Latest degree
Bachelor
Other areas of specialty/work
Nursery
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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

No - There is not 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