

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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 receive 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 ( $\geq 160 / 100$  mmHg); ② myocardial infarction and unstable angina ■ History of severe central nervous system events ■ Known 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**  
Pirfenidone 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 ( $\geq 160 / 100$  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**

In 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 researches 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**

Shivering

#### **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

##### **City**

Kermanshah

##### **Province**

Kermanshah

##### **Postal code**

6715847141

##### **Phone**

+98 83 3427 4618

##### **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

**Street address**

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

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3835 8258

**Email**

daftarriast@kums.ac.ir

**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

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Baghabrisham Ave., Parastar Blvd., Medicine school

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3427 4618

**Email**

bahareh.baghchi@kums.ac.ir

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Bahareh Baghchi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Baghabrisham Ave., Parastar Blvd., Medicine school

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3427 4618

**Email**

bahareh.baghchi@kums.ac.ir

## Person responsible for updating data

**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Mohammad Nazarian Pirdoosti

**Position**

nursing student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Farabi Hospital, Dollat Abad, Kermanshah, Iran

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 4512 6851

**Email**

mnazarianpirdosti@gmail.com

## 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