# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Safety and Efficacy of PHR 160 Spray on the Outcomes of Patients With COVID-19 a Multi-center Randomized Blinding Clinical Trial Study

## Protocol summary

**Study aim**

Determining the safety and efficacy of PHR160 spray on the outcomes of patients with COVID-19,a multicenter randomized clinical trial

**Design**

A clinical trial with a control-group; with parallel, Triple-blinded ,and blocks 4 and6 will be used for randomization.From each center,56 definite Covid-19 patients will be selected and randomly divided into two groups of 28people,so total of 224 patients will be included in the study.In the intervention-group, patients will receive standard treatment in addition to receiving test spray.

**Settings and conduct**

This study is a multi-center randomized,controlled, and blinded clinical-trial study that will be performed In the centers under the supervision of five universities of medical sciences, including Baqiyatallah,Hormozgan,Bushehr,Jundishapur and Kermanshah.In this study, the samples will be selected from patients with COVID-19 using convenience sampling and based on entry-criteria and will be randomly divided into two groups,including a control-group and an intervention-group.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: hospitalized Patients with COVID-19; Informed consent. Exclusion criteria: Patients with HIV; Patients with cancer undergoing chemotherapy.

**Intervention groups**

In both groups, hydroxychloroquine 400 mg (first day only) / naproxen 250 mg every 12 hours (for five days) / 500 mg azithromycin on the first day and 250 mg on the second to fifth days / 40 mg of famotidine every 12 hours for five days and 25 mg prednisone (daily) for five days will be given to patients. In the experimental group, an oral puff of PHR160 spray will be given to the patients hourly with spacer, ten times a day for ten days, and placebo spray will be used in the control group

**Main outcome variables**

Primary outcome: Shortness of breath. Secondary outcome: hospitalization length; response to treatment based on radiological findings.

## General information

**Reason for update**

change Expected recruitment end date and And change a Typographical mistakes

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20200731048257N1**
Registration date: **2020-11-08, 1399/08/18**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-02, 1399/09/12**
Update count: **1**

**Registration date**

2020-11-08, 1399/08/18

**Registrant information**

**Name**

Mehran Pouraqajani

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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+98 21 8856 8654

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himehran95@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-08-15, 1399/05/25

**Expected recruitment end date**

2021-03-05, 1399/12/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Safety and Efficacy of PHR 160 Spray on the Outcomes of Patients With COVID-19 a Multi-center Randomized Blinding Clinical Trial Study

**Public title**

Safety and Efficacy of PHR 160 Spray on the Outcomes of Patients With COVID-19

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

informed consent to participate in the study Patients 18 to 75 years of age with COVID-19 who have been diagnosed with PCR Strong clinical suspicion of covid 19 with positive findings in CT Scan Shortness of breath

**Exclusion criteria:**

Patients with HIV Patients with cancer undergoing chemotherapy Patients receiving Immune Mediators Patients need hospitalization in the intensive care unit Patients with uncontrolled heart, kidney or liver failure Pregnant or lactating women Intolerance to the drugs used in this study (symptoms such as diarrhea, nausea, vomiting and respiratory problems)

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **224**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

To assign patients to two groups, the method of Permuted Balanced Block Randomization with the size of 4 and 6 random blocks will be used. Also, a unique code will be produced for each person and the medicines will be labeled using the mentioned codes and will be provided to the centers. Randomization will be done separately for each center and the effects of the centers will be adjusted in the analysis. The randomization sequence will be done in the Central Committee and separately for the centers. The randomization sequence will be generated and maintained by the epidemiologist colleague.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

Because the medications are labeled, the patient will not know exactly who is taking the original medication or the placebo, and the intervener who will give the medication to the patient will not be aware of this. Also, the evaluator of the results will be given only the patient code and the drug label code.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

### 1

**Registry name**

مرکز ثبت کارآزمائي هاي باليني ايالات متحده آمريکا

**Secondary trial Id**

NCT04463420

**Registration date**

2020-08-07, 1399/05/17

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

The Ethics Committee of the Baqiyatallah University of Medical Sciences

**Street address**

Mollasadra

**City**

Tehran

**Province**

Tehran

**Postal code**

1435916471

**Approval date**

2020-05-16, 1399/02/27

**Ethics committee reference number**

IR.BMSU.REC.1399.176

## Health conditions studied

### 1

**Description of health condition studied**

COVID-19

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19, virus identified

## Primary outcomes

### 1

**Description**

Dyspnea

**Timepoint**

The beginning of the study and the fifth day

**Method of measurement**

shortness of breath measured by Visual analog scale (VAS) dyspnea score. The minimum score is zero means shortness of breath and the highest score is 10 means the maximum intensity of shortness of breath.

## Secondary outcomes

### 1

**Description**

Length of hospitalization

**Timepoint**

At the end of hospitalization

**Method of measurement**

The length of time the patient is hospitalized after the diagnosis of COVID-19

### 2

**Description**

Radiological Response

**Timepoint**

The first and fourteenth day of study

**Method of measurement**

CT scan

### 3

**Description**

Mortality

**Timepoint**

At the end of hospitalization

**Method of measurement**

Duration of the day from hospitalization to discharge (acceptable recovery) or death based on Patient medical records

### 4

**Description**

Allergy to medication

**Timepoint**

daily

**Method of measurement**

Questionnaire

### 5

**Description**

Laboratory Response

**Timepoint**

at first day an fifth day

**Method of measurement**

Normal blood cell count and CRP count (normal laboratory range)

### 6

**Description**

O2 saturation without supplemental oxygen

**Timepoint**

Every six hours and at the end of the treatment and discharge period

**Method of measurement**

Using an oximeter pulse, the amount of oxygen saturation is measured. If the patient is receiving oxygen, first cut off the oxygen for 5 minutes and then measure. If the oxygen drops below 90 degrees, oxygen therapy will be re-established immediately.

### 7

**Description**

Adverse reactions to medication

**Timepoint**

daily

**Method of measurement**

physical examination

## Intervention groups

### 1

**Description**

Intervention group: : Hydroxychloroquine 400 mg only on the first day / one naproxen 250 mg every 12 hours for 5 days / 500 mg azithromycin on the first day and 250 mg on the second to fifth days / 40 mg famotidine every 12 hours for 5 days / 25 mg prednisolone daily for 5 days / PHR160 spray one hour oral puff with Demyar ten times a day for ten days in a row, for ten days.

**Category**

Treatment - Drugs

### 2

**Description**

Control group: Hydroxychloroquine 400 mg only on the first day / one naproxen 250 mg every 12 hours for 5 days / 500 mg azithromycin on the first day and 250 mg on the second to fifth days / 40 mg famotidine every 12 hours for 5 days Daily / 25 mg prednisolone daily for 5 days / placebo spray one hourly oral puff ten times a day for ten days in a row, for ten days

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Centers under the supervision of Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Mahdi Bagheri

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**2**

**Recruitment center**
**Name of recruitment center**
Centers under the supervision of Hormozgan University of Medical Sciences
**Full name of responsible person**
Reza Mohtashami
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**3**

**Recruitment center**
**Name of recruitment center**
Centers under the supervision of Baqiyatallah University of Medical Sciences
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Reza Mohtashami
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**4**

**Recruitment center**
**Name of recruitment center**
Centers under the supervision of Ahwaz Jundishapur University of Medical Sciences
**Full name of responsible person**
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**5**

**Recruitment center**
**Name of recruitment center**
Centers under the supervision of Kermanshah University of Medical Sciences
**Full name of responsible person**
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Bagheiat-allah 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**
Bagheiat-allah 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**
Bagheiat-allah University of Medical Sciences

**Full name of responsible person**
Milad Asghardoost rezaei

**Position**
Medicine student

**Latest degree**
A Level or less

**Other areas of specialty/work**
General Practitioner

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## Person responsible for scientific inquiries

**Contact**

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**Position**
Assistant Professor

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Medical Pharmacy

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## Person responsible for updating data

**Contact**

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Mehran Pouraqajani

**Position**
Bachelor

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Bachelor

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Nursery

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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**
Deidentified IPD related to outcome will be shared.

**When the data will become available and for how long**
The access period will begin 6 months after publication of the paper

**To whom data/document is available**
The data will be available only for academic researchers.

**Under which criteria data/document could be used**
Only meta-analysis in collaboration with the current study research team will be permitted.

**From where data/document is obtainable**
Researchers can request data by emailing Dr.Reza mohtashami (reza_mohtashami1979@yahoo.com)

**What processes are involved for a request to access data/document**
Requested data will be sent by email after consideration

and approval by the relevant authorities from Baghiattallah university.

**Comments**