# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

31 May 2026

## Evaluation of the effectiveness of PHR-160 spray in hospitalized COVID-19 patients with severe lung involvement in improving oxygen saturation; a randomized clinical trial study

## Protocol summary

**Study aim**

The effectiveness of phr-160 spray in improving the respiratory status of Covid-19 patients in the emergency department

**Design**

Clinical trial with control group, parallel groups, randomized, phase 1 on 240 patients. Excel software rand function was used for randomization

**Settings and conduct**

This multicenter study is in coordination with Baqiyatallah Hospital / Martyrs of Tajrish Hospital / Khorshid Hospital of Isfahan. After confirming the patient's pulmonary involvement in favor of Covid-19 with CT scan and obtaining informed consent from the patient and checking the inclusion / exclusion criteria, they enter the study.

**Participants/Inclusion and exclusion criteria**

Inclusion creteria: Both sexes, Ages 15-75, Oxygen saturation percentage between 88 and 93% Confirmation of 19 patients by RT-PCR, Confirmation of Covid-19 using CT scan, Signing a informed consent form Exclusion creteria: Both sexes, Ages 15-75, Oxygen saturation percentage between 88 and 93%. Confirmation of 19 patients using RTPCR. Confirmation of Covid-19 using CT scan, Signing a informed consent form

**Intervention groups**

Treatment group: Inhalation of PHR-160 spray one puff per hour with Damiar during 6 hours after randomization in emergency depatment + standard emergency treatment Control group: Standard emergency treatment based on protocol Naproxen 250 mg, one tablet Famotidine 40 mg, one tablet Vitamin C 500 mg, one tablet

**Main outcome variables**

Primary outcome: 1. Comparison of oxygen saturation percentage in two intervention groups after randomization 2. Mean changes in oxygen saturation percentage after the intervention compared to oxygen saturation percentage at the beginning of the patient's entry into two intervention groups

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20201223049816N1**
Registration date: **2021-01-11, 1399/10/22**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-11, 1399/10/22**
Update count: **0**

**Registration date**

2021-01-11, 1399/10/22

**Registrant information**

**Name**

Fahimeh Shahjoei

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 8860 0067

**Email address**

fshahjooei@yahoo.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-12-20, 1399/09/30

**Expected recruitment end date**

2021-03-17, 1399/12/27

**Actual recruitment start date**

empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Evaluation of the effectiveness of PHR-160 spray in hospitalized COVID-19 patients with severe lung involvement in improving oxygen saturation; a randomized clinical trial study

**Public title**
Evaluation of the effectiveness of PHR-160 spray in hospitalized patients with Covid-19
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Both sexes Ages 15-75 Oxygen saturation percentage between 88 and 93%. Confirmation of 19 patients using RTPCR. Confirmation of Covid-19 using CT scan Signing a informed consent form
**Exclusion criteria:**
Attending another trial in the last three months pregnancy/lactation drug sensitivity to the ingredients in the intervention very high severity of the disease in the emergency room (consciousness less than 15 / oxygen concentration less than 88%, etc) history of chronic respiratory disease Previous pulmonary embolism (last three months)
**Age**
From **15 years** old to **75 years** old
**Gender**
Both

**Phase**
1
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **240**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Data collection and data management will be done using electronic patient report forms and electronic data management system, and the steps of data cleaning and locking and data monitoring will be done on-line during the study.This set of forms is required for the initial assessment of the patient and the necessary examinations to determine the presence of COVID-19 disease and a checklist of exclusion and inclusion conditions. If patients are eligible to enter the study , they will enter the randomization stage and start the intervention. It is necessary to have this separate form set to prepare a Participant flow table according to the consort reporting standard.
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Baqiyatallah University of Medical Sciences
**Street address**
Baqiyatallah Hospital, Mollasadra Ave., Vanak Square ., Tehran
**City**
Tehran
**Province**
Tehran
**Postal code**
1435915371
**Approval date**
2020-12-14, 1399/09/24
**Ethics committee reference number**
IR.BMSU.REC.1399.495

## Health conditions studied

### 1

**Description of health condition studied**
covid-19
**ICD-10 code**
U07.1
**ICD-10 code description**
COVID-19

## Primary outcomes

### 1

**Description**
Percentage of oxygen saturation in two intervention groups after randomization
**Timepoint**
1. After randomization at the beginning of the patient's arrival, and every day
**Method of measurement**
Using Pulse Oximeter

## Secondary outcomes

### 1

**Description**
The time required to reduce at least one grade of disease severity according to the Covid-19 national guideline
**Timepoint**

Every day

**Method of measurement**

Data collection and data management will be done using electronic patient report forms and electronic data management system, and the steps of data cleaning and locking and data monitoring will be done on-line during the study.

**2**

**Description**

Number and percentage of patients with adverse events and number and percentage of total adverse events

**Timepoint**

Evry day

**Method of measurement**

Data collection and data management will be done using electronic patient report forms and electronic data management system, and the steps of data cleaning and locking and data monitoring will be done on-line during the study.

## Intervention groups

**1**

**Description**

Intervention group: 1. Phr-160 spray group: PHR spray:160 micrograms per puff, 1 puff every 1 hour up to ten times a day, on days 1 to 10 (use of Damir is required) in addition to the latest covid-19 treatment in the country protocol. Due to the clinical symptoms, this treatment protocol can be continued for 10 days if needed.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Standard emergency treatment based on protocol, Naproxen 250 mg , Famotidine 40 mg , Vitamin C 500 mg

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Fahime Shahjoei

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Baqiyatallah university of Medical science, Mollasadra Ave., Vanak Square ., Tehran-

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**2**

**Recruitment center**

**Name of recruitment center**

Shohadaye Tajrish Hospital

**Full name of responsible person**

Amir Hossein Ghazale

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

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**Full name of responsible person**

Mostafa Ghanei

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mghaneister@gmail.com

**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**

30

**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**
Seyed Hassan Saadat
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Assistanc professor
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Amir Hosein Ghazale
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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**
Yes - There is 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
**Title and more details about the data/document**
Data can potentially be shared after people are not identifiable, but some data, such as information about the main outcome or the like, can be shared.
**When the data will become available and for how long**
The access period will start 6 months after the results are published
**To whom data/document is available**
The data will be available to researchers working in academic and scientific institutions
**Under which criteria data/document could be used**
The use of data will be allowed with the permission of the

authors and obtaining written consent

**From where data/document is obtainable**

Dr. Fahimeh Shahjoui in Baqiyatallah Hospital.

**What processes are involved for a request to access data/document**

At the request of the applicant, the principal of the project can provide the license to the applicant within 3 months.

**Comments**