Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 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)

Phone

+98 21 8856 8654

Email address

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

Street address

Mollasadra

City

Tehran

Province

Tehran

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1435916471
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mbagheri.pharm@gmail.com
Web page address

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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Hormozgan
Province
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07633317297
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3

Recruitment center
Name of recruitment center
Centers under the supervision of Baqiyatallah University of Medical Sciences
Full name of responsible person
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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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reza_mohtashami1979@yahoo.com
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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
Reza Mohtashami
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Dr. Reza Mohtashami
Street address
MollaSadra
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Tehran
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Phone
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Email
reza_mohtashami1979@yahoo.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

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

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

Full name of responsible person
Mahdi Bagheri

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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mbagheri.pharm@gmail.com

Person responsible for updating data

Contact

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

Full name of responsible person
Mehran Pouraqajani

Position
Bachelor

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
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Postal code
1435916471

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Email
himehran95@gmail.com

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