Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Evaluation of the effectiveness of PHR-160 spray in recovery of hospitalized patients with Covid-19 in Isfahan province in 1399

Protocol summary

Study aim
Evaluation of the effectiveness of PHR-160 spray in recovery of hospitalized patients with Covid-19 in Isfahan province in 1399

Design
Clinical trial with control group, with parallel groups, blind, randomized, phase 2 on 198 patients. RANDOM SAMPLING SPSS software was used for randomization.

Settings and conduct
Type of study Randomized clinical trial, two parallel groups, blinded Study community: Patients hospitalized with Covid-19 with pulmonary involvement in Khorshid Hospital in Isfahan

Participants/Inclusion and exclusion criteria
Inclusion criteria Age more than 18 years Definite diagnosis of SARS-CoV-2 virus based on PCR Diagnosis of pneumonia consistent with lung involvement with COVID-19 on CT scan Criteria for non-entry Having comorbidities (chronic kidney failure, cirrhosis, severe heart failure (less than 25% EF), active or untreated cancer) Pregnancy and breastfeeding Patients with hepatic enzymes including aspartate transaminase (AST) and alanine transaminase (ALT) at 5 times more than normal amount Requirement to be admitted to the ICU at the beginning of hospitalization

Intervention groups
Intervention and control group: 1. Intervention group: PHR 160 spray, which contains 160 micrograms of active ingredient in each puff, 2 puffs every 2 hours during the awakening period using Damiar with national standard treatment 2. Control group: placebo spray containing proplant (HFA gas which is a carrier and inert) in double puff every 2 hours (except sleeping hours), along with the national standard treatment

Main outcome variables
• Duration and severity of symptoms (cough and shortness of breath) • Duration of hospitalization • Blood oxygen levels • Requirement for ICU admission • Duration of hospitalization in the ICU • Death rate

General information

Reason for update

Acronym
ISF PHR-160 Study

IRCT registration information
IRCT registration number: **IRCT20200411047029N1**
Registration date: **2021-04-24, 1400/02/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-24, 1400/02/04**
Update count: **0**

Registration date
2021-04-24, 1400/02/04

Registrant information

Name
Ramin Sami

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3222 2892

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r.sami@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-21, 1400/02/01

Expected recruitment end date
2021-05-21, 1400/02/31

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 recovery of hospitalized patients with Covid-19 in Isfahan province in 1399

Public title
Effectiveness of PHR-160 spray in recovery of hospitalized patients with Covid-19 in Isfahan province in 1399

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age more than 18 years Definite diagnosis of SARS-CoV-2 virus based on PCR Diagnosis of pneumonia consistent with lung involvement with COVID-19 on CT scan Need to be admitted to the ICU at the beginning of hospitalization

Exclusion criteria:
Having comorbidities (chronic kidney failure, cirrhosis, severe heart failure (less than 25% EF), active or untreated cancer) Pregnancy and breastfeeding Patients with hepatic enzymes including aspartate transaminase (AST) and alanine transaminase (ALT) at 5 times more than normal amount

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **198**

Randomization (investigator's opinion)
Randomized

Randomization description
If patients agree to participate, they will be placed in one of two intervention or control groups in the random allocation project using SPSS software. For this purpose, they are numbered from 1 to 198 in SPSS software. Then, using RANDOM SAMPLING, we select 50% of the samples and place the selected samples in the CASE group and the deleted samples in the control group. Intervention and control group: 1. Intervention group: PHR 160 spray, which contains 160 micrograms of active ingredient in each puff, 2 puffs every 2 hours during the awakening period using Damiar with national standard treatment 2. Control group: placebo spray containing proplant (HFA gas which is a carrier and inert) in double puff every 2 hours (except sleeping hours), along with the national standard treatment

Blinding (investigator's opinion)
Triple blinded

Blinding description
Blinding: Three-way blind Blind groups in the study: participant research fellow Analyzer The study will be blinded in three ways. Patients will be blinded to the type of intervention, as well as the researcher who must enter the data into the relevant checklist, and the data analyzer will be blinded to the type of intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
School of Medicine, Isfahan University of Medical Sciences

Street address
Hezar Jarib

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Approval date
2021-04-11, 1400/01/22

Ethics committee reference number
IR.MUI.MED.REC.1400.020

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
Duration and severity of symptoms (cough and shortness of breath)

Timepoint
Daily

Method of measurement
Case file-Query from patients

2

Description
Duration of hospitalization

Timepoint

Daily
Method of measurement
Case file

3

Description
Blood oxygen levels
Timepoint
Daily
Method of measurement
Pulse Oximeters

4

Description
Requirement for ICU admission
Timepoint
Daily
Method of measurement
Doctor diagnosis

5

Description
Duration of hospitalization in the ICU
Timepoint
Daily
Method of measurement
Case file

6

Description
Death rate
Timepoint
Daily
Method of measurement
Case file

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: PHR 160 spray, which contains 160 micrograms of active ingredient in each puff, 2 puffs every 2 hours during the awakening period using Damiar with national standard treatment
Category
Treatment - Drugs

2

Description
Control group: Placebo spray containing proplant (HFA gas that is carrier and inert) in two puffs every 2 hours (except sleeping hours), along with the national standard treatment
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Ramin Sami
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2

Recruitment center
Name of recruitment center
Khorshid Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The Research Institute of Food and Secrets TAAMASRAR
Full name of responsible person
hamidreza shekhroshandel
Street address
Unit 2, Corner of Hazrat Abolfazl St., Marzdaran Boulevard, Ashrafi Esfahani Boulevard, Tehran

City
Tehran
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Postal code
1461744366
Phone
+98 21 4425 4747
Email
info@taamasrar.com
Web page address
http://sibdiet.com/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
The Research Institute of Food and Secrets TAAMASRAR

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Ramin Sami
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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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

After de-identifying the outcome data

When the data will become available and for how long

Six months after the article is published

To whom data/document is available

The data will only be available to researchers working at academic institutions.

Under which criteria data/document could be used

In order to spread the knowledge and with the permission of the research team

From where data/document is obtainable

The person responsible for updating the data

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

Via email after evaluation

Comments