

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)

Phone

+98 31 3222 2892

Email address

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 propland (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

Isfahan

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 propland (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
Street address
Sofe Blvd.
City
Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 3668 5555
Email
alzahra@mui.ac.ir
Web page address
<http://alzahra.mui.ac.ir>

2

Recruitment center
Name of recruitment center
Khorshid Hospital
Full name of responsible person
Dr. Ramin Sami
Street address
Ostandari
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3222 2127
Email
nour@mui.ac.ir
Web page address
<http://nour.mui.ac.ir>

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
Province
Tehran
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
Internal Medicine
Street address
Hezar Jarib
City
Isfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3222 2892
Email
r.sami@med.mui.ac.ir
Web page address

Person responsible for scientific 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
Internal Medicine
Street address
Hezaer Jarib
City
Isfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3222 2892
Email
r.sami@med.mui.ac.ir
Web page address

Person responsible for updating data

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
Internal Medicine
Street address
Isfahan
City
Isfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3222 2892
Email
r.sami@med.mui.ac.ir

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