Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

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Email address
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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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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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
Position
Assistanc professor
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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