

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Determining the effect of Pinen.Hydronoplacton.Ribonucleic acid (PHR) spray on reducing the length of hospital stay of patients with Covid-19

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Determining the effect of Pinen.Hydronoplacton.Ribonucleic acid (PHR) spray in reducing the length of hospital stay of patients with Covid-19

Last update: **2021-04-20, 1400/01/31**

Update count: **0**

Registration date

2021-04-20, 1400/01/31

Design

A phase 2 clinical trial with control and intervention groups, with parallel, non-blind, randomized, groups on 188 patients. Clustering method was used for randomization

Registrant information

Name

Fatemeh Shirvanizade arani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5472 5800

Email address

dr.shirvanizade@gmail.com

Settings and conduct

This study is a randomized clinical trial that will be performed in the Hospitals of Kashan University of Medical Sciences. Samples will be selected from patients with COVID-19 based on inclusion criteria and patients will be randomly divided into two groups including a control group and an intervention group.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Male or female patients aged 18 to 75 years with COVID-19 who have been diagnosed by PCR or clinical examination and lung scan; Informed consent by the patient or patient companion to participate in the study

Expected recruitment start date

2021-03-04, 1399/12/14

Expected recruitment end date

2021-05-04, 1400/02/14

Intervention groups

Intervention group: In addition to the routine treatment regimen, patients will receive 1 puff of PHR spray (160 micrograms per puff) every 1 hour to ten times a day on days 1 to 10. The control group will receive the usual treatment in accordance with the national protocol.

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Percentage of oxygen saturation, dyspnea, and severity of cough

Trial completion date

empty

General information

Scientific title

Determining the effect of Pinen.Hydronoplacton.Ribonucleic acid (PHR) spray on reducing the length of hospital stay of patients with Covid-19

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210222050457N1**

Registration date: **2021-04-20, 1400/01/31**

Public title

Determining the effect of

Pinen.Hydronoplacton.Ribonucleic acid (PHR) spray in reducing the length of hospital stay of patients with Covid-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male or female patients aged 18 to 75 years with COVID-19 who have been diagnosed with a lung scan, PCR, or clinical examination. Obtaining informed consent from the patient or patient caregiver to participate in the study

Exclusion criteria:

Cancer patients undergoing chemotherapy Patients with immunodeficiency diseases receiving immunomodulators Patients with uncontrolled heart, kidney or liver failure Women who are pregnant or breastfeeding Patients with low level of consciousness who are not able to inhale the spray

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **188**

Randomization (investigator's opinion)

Randomized

Randomization description

First, the intervention and control groups were coded with the letter A and Bm respectively, and then randomization list will be prepared using the website www.sealedenvelope.com/simple-randomiser/v1/lists via selecting a sample size of 188 (two groups of 94) and permuted block randomization method (block size=4), (47 blocks of 4). Then, the subjects included in the study will be assigned to one of the two groups A or B through the obtained randomization list. For example, suppose that the permutation method is ABBA in the first four blocks, so the first and fourth samples will be assigned to group A and the second and third samples to group B, and the same will be continued until the last sample (188th person).

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 Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences, Qutb Ravandi Blvd., Kashan

City

Kashan

Province

Isfahan

Postal code

8715973474

Approval date

2021-02-19, 1399/12/01

Ethics committee reference number

IR.KAUMS.REC.1399.047

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

Percentage of arterial oxygen saturation

Timepoint

Before and after intervention on a daily basis

Method of measurement

Pulse oximeter

2

Description

Severity of cough

Timepoint

Before and after intervention on a daily basis

Method of measurement

Based on the degree of severity

3

Description

Shortness of breath

Timepoint

Before and after intervention on a daily basis

Method of measurement

Based on the degree of severity

Secondary outcomes

1

Description

Length of stay in hospital

Timepoint

By day

Method of measurement

Number of days

2

Description

ICU admission time

Timepoint

By day

Method of measurement

Number of days

Intervention groups

1

Description

Intervention group: In addition to the routine treatment regimen, patients will receive a puff of PHR spray 160 (6 micrograms per puff) using a spacer, 10 times a day during 10 days. PHR160 spray made by Jabr Ibn Hayan Pharmaceutical Company was used in this trial.

Category

Treatment - Drugs

2

Description

Control group: They will receive control of the usual treatment for the disease according to the normal treatment regimen of the hospital including one 250 mg naproxen tablet 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, and 25 mg prednisolone daily for 5 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Shahid Beheshti Hospital

Full name of responsible person

Fatemeh Shirvanizadeh Arani

Street address

Shahid Beheshti hospital complex, Qotb -e Ravandi Blvd, km 5 of Ravand road, Kashan

City

Kashan

Province

Isfahan

Postal code

87159/81151

Phone

+98 31 5472 5800

Email

dr.shirvanizade@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Fatemeh Shirvanizadeh Arani

Street address

Kashan University of Medical Sciences, Qotb -e Ravandi Blvd., Kashan

City

Kashan

Province

Isfahan

Postal code

87159/81151

Phone

+98 31 5472 5800

Email

dr.shirvanizade@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan University of Medical Sciences

Proportion provided by this source

50

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

Kashan University of Medical Sciences

Full name of responsible person

Reza Razzaqi

Position

Physician

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Kashan University of Medical Sciences, Qotb –e
Ravandi Blvd., Kashan

City

Kashan

Province

Isfahan

Postal code

8715973474

Phone

+98 31 5472 5800

Email

rrazzaghi33@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Aran O Bidgol Health Center

Full name of responsible person

Fatemeh Shirvani Arani

Position

Physician

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

Health Center, Imam Khomeini Boulevard, Aran O Bidgol

City

Aran O Bidgol

Province

Isfahan

Postal code

8741646949

Phone

+98 31 5472 5800

Email

Dr.shirvanizade@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Afshar

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Nursery

Street address

Kashan University of Medical Sciences, Qotb –e
Ravandi Blvd., Kashan

City

Kashan

Province

Isfahan

Postal code

88141-87159

Phone

+98 31 5472 5800

Email

afshar_m_1344@yahoo.com

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

Undecided - It is not yet known if there will be 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