Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Assessment of the effect of Pinen.Hydronoplacton.Ribonucleic acid (PHR) spray in pulmonary problems of the patients with Covid-19

Protocol summary

Study aim

Assessment of the effect of Pinen.Hydronoplacton.Ribonucleic acid(PHR) spray in pulmonary problems of the patients with Covid-19

Design

Randomization method is cluster randomization.Randomization units are hospitalized wards. First, two inpatient wards (capacity of each ward is 32 patients) are selected with similar conditions and, as two clusters, are randomly assigned to the intervention and control group. Referral to departments in the intervention group and control group is based on the patient's turn and is not related to the patient's condition or severity of the disease. patients admitting method in two wards will cause approximately similarities between two clusters before randomization. This study has no concealment and patients in the intervention group will receive the intervention medication in addition to the routine treatment, but in the control group they will only receive the routine treatment. Study Phase:2-3.Blinding is not done.

Settings and conduct

In addition to the usual medicines for coronavirus, participants in the drug group take the spray for ten days and ten times daily (every hour, once). The control group only uses current medicine. The study site is Baqiyatallah Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Male or female patients 18-65 years with COVID-19 confirmed by PCR and Ground glass view on CT scan.arterial oxygen saturation of less than 93%.completed informed consent Exclusion criteria:pregnancy, ulcer or oral malignancy, history of pulmonary malignancy,history of asthma or COPD.

Intervention groups

The intervention groups will be two.In addition to the usual medicines for coronavirus, participants in intervention group take the spray .The control group only uses current medicine.

Main outcome variables

3D CT Scans dyspnea cough arterial oxygen saturation Respiratory Rate (RR) CBC diff

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160131026298N2**
Registration date: **2020-04-20, 1399/02/01**
Registration timing: **retrospective**

Last update: **2025-01-04, 1403/10/15**
Update count: **2**

Registration date

2020-04-20, 1399/02/01

Registrant information

Name

Ahmad Reza Sharifi Olounabadi

Name of organization / entity

Baqiatallah University of Medical Science, Department of Traditional Iranian Medicine

Country

Iran (Islamic Republic of)

Phone

+98 21 8804 0060

Email address

a-sharifi@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-10, 1398/12/20

Expected recruitment end date

2020-03-15, 1398/12/25

Actual recruitment start date

2020-03-10, 1398/12/20

Actual recruitment end date

2020-03-15, 1398/12/25

Trial completion date

2020-03-24, 1399/01/05

Scientific title

Assessment of the effect of Pinen.Hydronoplacton.Ribonucleic acid (PHR) spray in pulmonary problems of the patients with Covid-19

Public title

The effect of PHR spray on patients with coronavirus-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male or female patients 18-65 years with COVID-19 confirmed by PCR (with mild involvement) - Ground glass view on CT scan - Arterial oxygen saturation less than 93% - Breathing more than 24 times per minute - At the Beginning onset of the disease - Negative pregnancy test in women - Completion of informed consent form by patient or supervisor

Exclusion criteria:

Oral ulcer or malignancy - history of pulmonary malignancy - history of asthma or COPD

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **64**

Actual sample size reached: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method is cluster randomization.Randomization units are hospitalized wards. First, two inpatient wards (capacity of each ward is 32 patients) are selected with similar conditions and, as two clusters, are randomly assigned to the intervention and control group. Referral to departments in the intervention group and control group is based on the patient's turn and is not related to the patient's condition or severity of the disease. patients admitting method in two wards will cause approximately similarities between two clusters before randomization. This study has no concealment and patients in the intervention group will receive the intervention medication in addition to the routine treatment, but in the control group they will only receive the routine treatment.

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 University of Medical Sciences, Shahid Nosrati Alley, Shaikh Bahai St., Vanak Square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2020-03-10, 1398/12/20

Ethics committee reference number

IR.BMSU.REC.1398.387

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.2

ICD-10 code description

U07.2COVID-19, virus not identified, COVID-19

Primary outcomes

1

Description

Measurement of cough severity

Timepoint

Day 1 before and at the end of treatment

Method of measurement

Standard cough questionnaire

2

Description

severity of shortness of breath

Timepoint

Day 1 before and at the end of treatment

Method of measurement

Shortness Of Breath With Daily Activity (SOBDA) Questionnaire

3

Description
lung radiologic changes
Timepoint
At beginning and end of the study
Method of measurement
Chest CT scan

Secondary outcomes

1

Description
CBC Test
Timepoint
At beginning and end of the study
Method of measurement
Intravenous blood sampling and standard blood cell counter device

Intervention groups

1

Description
Intervention group:The group uses the following herbal medicine in addition to the current medicine for Covid-19: Drug Name: Pinene-Hydronoplactone-Ribonucleoic-Abbreviation: PHR160 - Drug Form: Inhaler Spray --- Ingredients: Sineol Menthol Crocin Safranol Alpha Tojun Oleic Acid Linoleic Acid Linolenic AcidIt was extracted from natural products found in 7 plant species by steam distillation method. These herbs have previously had a single, double or triple human consumption history. Effectives per puff: 160 micrograms How to use PHR160: Determine the dosage approach for the above product based on the following: 1. Due to the volume of the nozzle output and pump MDIs and the presence of propylant (HFA gas) and alcohol in the product concentration of essential oils and herbal compounds in the total MDI is about 0.3%. Therefore, the total amount of soluble natural substances available per puff is less than 300 nL or 270 mg, which, of course, reaches a limited proportion in the lungs. 1-20 g / kg of human body weight and these compounds are considered very safe and high dosage is much lower than the toxic range indicated and is 1/100 toxic in the case of essential oils.3. Products available on the market such as Eucalyptus Barrage incense, Eucalyptus dyne incense Pulmonary doses of essential oils are similar to our product compounds in excess of 30mg. Of the amount in each puff investigated product is less than 1/100 of the amount above 0.4. External products mainly used in Aroma Therapy Ascents, MBC Aerosol, Primatene Mist are examples of those with higher doses of essential oil.5.Refruitment time to discuss the use or inhalation of the above product 30-45 In this case, the maximum time interval of 1 hour of awakening has been suggested for this product to reach the maximum dose possible with this product. Highly effective at the same time as the above dosage and the regimen, it was suggested to administer once per waking hour to be used in preliminary studies. It's the day. The spray was formulated by Jaber ebne Hayyan Pharmaceutical Company and the entire project is owned by the taam asrar Research Institute, Baqiyatallah University of Medical Sciences and Jaber Bin Hayan Pharmaceuticals.
Category
Treatment - Drugs

2

Description
Control group: This group only uses current medicine (according to the Ministry of Health protocol) for the new corona virus.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah Hospital
Full name of responsible person
REZAMOHTASHAMI; AHMAD REZA SHARIFI OLOUNABADI
Street address
Mulla Sadra Street, Vanak Square, After Sheikh Baha'i, Baqiyatallah Hospital
City
Tehran
Province
Tehran
Postal code
1435915371
Phone
+98 21 8805 0436
Email
a-sharifi@bmsu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Alireza Shahriary
Street address
Baqiyatallah University, Third Floor, Vice-Chancellor for Research and Technology, Sheikh Bahai St, Mulla Sadra St,Vanak Square
City
Tehran
Province
Tehran
Postal code
1435916471
Phone

+98 21 8755 5250

Email

a-sharifi@bmsu.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

www.taamasrar.com

Proportion provided by this source

10

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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Ahmad Reza Sharifi Olounabadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Vice-Chancellor for Research and Technology, Third Floor, Baqiyatallah University, Sheikh Bahaei St, Mulla Sadra St, Vanak Square

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8755 5250

Email

a-sharifi@bmsu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Reza Mohtashami

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Baqiyatallah University of Medical Sciences,Sheikh Bahai Street, Molla Sadra Street, Vanak Square

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8755 5250

Email

reza_mohtashami1979@bmsu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Ahmad Reza Sharifi Olounabadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Baqiyatallah University of Medical Sciences,Sheikh Bahai Street, Molla Sadra Street, Vanak Square

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8755 5253

Email

a-sharifi@bmsu.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

Questionnaires and related paraclinic tests in cases of discretion

When the data will become available and for how long

The next three to six months

To whom data/document is available

Approved faculty members and professors

Under which criteria data/document could be used

Use for spreading science and under legal terms and organizational guidelines

From where data/document is obtainable

Vice chancellor for research of university

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

Send an email to the address of the Vice Chancellor for Research

Comments

Compliance with organizational requirements