Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluation of the effect of inhaled solution based on silver colloid with the brand name colloide silver nasal spray 10ppm to control COVID-19-induced lung infection and increase patients' respiratory volume

Protocol summary

Study aim

The aim of this study was to evaluate the effect of nano-solution in inhaled form using a nebulizer to prevent the development of infection in lung tissue and increase the respiratory capacity of patients with Covid-19.

Design

A clinical trial with a control group, with parallel, blind, randomized, phase 3 drug groups is performed on 40 patients. The lottery method is used for randomization.

Settings and conduct

In addition to receiving the medication prescribed in accordance with the national protocol, the patient receives the desired medication using a nebulizer. Medication: 1cc will be prescribed to check for possible side effects. The next dose will be administered to the patient 4 hours after the first dose in the amount of 2 cc and then for 72 hours and every 8 hours 3cc. The drug is placed in a nebulizer and given to the patient for 10-15 minutes. The study site is performed in a room with negative air pressure.

Participants/Inclusion and exclusion criteria

Inclusion criteria: -The patient's PCR test is positive, -The patient is not COPD - The patient does not have Acute kidney failure - The patient does not have Acute liver failure - The patient has low respiratory capacity. - 18 years and older, -The patient does not need ventilator therapy exclusion criteria:The patient will be present at another clinical trial, pregnant women

Intervention groups

This study consists of 2 groups of intervention and control. Intervention group: This group receives only the drug of the study by inhalation and using a nebulizer. Control group: This group does not receive placebo. Therefore, there is no intervention through study in the control group.

Main outcome variables

- The patient's respiratory capacity -Control lung infection - Laboratory signs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190226042851N1**
Registration date: **2020-10-05, 1399/07/14**
Registration timing: **retrospective**

Last update: **2020-10-05, 1399/07/14**
Update count: **0**

Registration date

2020-10-05, 1399/07/14

Registrant information

Name

Hakim Abiavy

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3378 7287

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hakim.abiavy76@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2020-09-19, 1399/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of inhaled solution based on silver colloid with the brand name colloide silver nasal spray 10ppm to control COVID-19-induced lung infection and increase patients' respiratory volume

Public title
Evaluation of the effect of nano-based inhalation solution to relieve shortness of breath in COVID-19 patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Positive PCR test The patient is not COPD Not having acute kidney problems The patient does not have Acute liver failure 18 years and older The patient does not need ventilator therapy The patient has low respiratory capacity The patient has covide-19

Exclusion criteria:
The patient is hospitalized for less than seven days

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
First, patients with inclusion criteria are selected. They are then selected based on simple randomization using the lottery method. To do this, the patients' names are written on paper and placed in a box, then the papers are taken out one by one until the desired sample size is complete.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This study is a supportive treatment that is implemented alongside the national protocol. In fact, the patient routinely receives the prescribed drug according to the approved protocol of the country and will receive the study drug as an additional or excess drug and has no interaction with the country's treatment protocol

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ahvaz Jundishapur University Ethics Committee

Street address
shahre daneshgahi Town

City
Ahwaz

Province
Khouzestan

Postal code
6135715794

Approval date
2020-06-20, 1399/03/31

Ethics committee reference number
IR.AJUMS.REC.1399.345

Health conditions studied

1

Description of health condition studied
sars-covid-19 - covid-19

ICD-10 code
U07.1

ICD-10 code description
COVID-19 Disease

Primary outcomes

1

Description
The patient's respiratory capacity

Timepoint
Before reading And is monitored daily during the study

Method of measurement
Encouraging spirometry device - pulse oximeter - clinical examination

2

Description
Control of the patient's pulmonary infection

Timepoint
Clinical examinations and measurements of the patient's body temperature are performed daily before the study and during the study - the patient's CT scan is taken before the start of the study and at the end of the study.

Method of measurement
Clinical examinations - mercury thermometer - CT scan

Secondary outcomes

1

Description
Compelet blood count

Timepoint
The first and last day of the study are monitored.
Method of measurement
Blood sampling from the patient

2

Description
Alkaline Phosphatase
Timepoint
The first and last day of the study are monitored.
Method of measurement
Blood sampling from the patient

3

Description
urine analysis
Timepoint
The first and last day of the study are monitored.
Method of measurement
Urine sampling of the patient

Intervention groups

1

Description
Intervention group: In addition to receiving the drug according to the national protocol, this group uses the drug under study by inhalation. The national protocol uses interferon beta-1a, interferon beta-1b, dexamethasone, prednisolone, corticosteroids, and heparin.This drug consists of deionized water and nano-sized silver particles with the chemical formula Ag. The equipment used in this study is only a nebulizer mask. Drug prescription: 1cc will be prescribed to investigate possible side effects of the drug. The next dose will be administered to the patient 4 hours after the first dose in the amount of 2 cc and then for 72 hours and every 8 hours 3cc. The drug is placed in a nebulizer and given to the patient for 10-15 minutes.
Category
Treatment - Drugs

2

Description
Control group: This study does not have a placebo, so patients in this group do not receive any medication from the study and receive medication according to the national protocol. The national protocol uses the drugs interferon beta-1a, interferon beta-1b, dexamethasone, prednisolone, corticosteroids and heparin. In addition to the patient's SPO2, history and clinical examination are taken from the patient.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi hospital
Full name of responsible person
Fatemeh ahmadi
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Felestin ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
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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
Ahvaz University of Medical Sciences
Proportion provided by this source
100
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
Ahvaz University of Medical Sciences
Full name of responsible person
Hakim abiavy
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
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Person responsible for updating data

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hakim.abiavy76@gmail.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