

# 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)

##### Phone

+98 61 3378 7287

##### Email address

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 covid-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

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##### City

Ahwaz

##### Province

Khuzestan

##### 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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## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Ahvaz University of Medical Sciences

##### **Full name of responsible person**

mohamad badavi

##### **Street address**

Shahre daneshgahi Town

##### **City**

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##### **Province**

Khouzestan

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##### **Email**

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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

drfayo@ajums.ac.ir

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
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Student  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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

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