# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Aug 2022

## Prophylaxis and treatment of COVID-19 using a nasal spray containing 3% dimethyl sulfoxide (DMSO) and 20% ethanol solution

## Protocol summary

**Study aim**

Effect of dimethyl sulfoxide (DMSO) and ethanol solution in the prevention of COVID-19 patients

**Design**

A clinical trial with a control group, with parallel groups, triple-blind, randomized, phase 3 on 440 patients. Excel software rand function was used for randomization.

**Settings and conduct**

This study will be performed on patients who are admitted to Imam Hossein hospital and health employees in Shahroud. Patients will randomly be allocated into two groups. The intervention group will receive dimethyl sulfoxide (DMSO) and ethanol solution inhalation spray and normal saline as a placebo for the control group respectively. This study performed as triple blinds.

**Participants/Inclusion and exclusion criteria**

-All outpatients with positive PCR tests with informed consent to participate in the study will be included. - Immigrants or those who are temporarily present in Shahroud, pregnant or lactating women, patients who develop an obsessive-compulsive disorder or anxiety due to interventions during the study, and non-compliance with the study protocol will be excluded. - Shahroud health employees

**Intervention groups**

The intervention group will receive dimethyl sulfoxide 3%(DMSO) inhalation spray and ethanol solution20%, and the control group will receive routine protocols and normal salin as placebo.

**Main outcome variables**

1. O2 Saturation (8, 14, 21) 2. Respiratory Rate (8, 14, 21) 3. Temperature (8, 14, 21) 4.Duration of hospital stay (at the end of the study) 5. Treatment outcome including recovery, ERDS, and duration of oxygen therapy (during the study period) 6. Need for intensive care and respiratory support (during the study period) 7. Time of separation from the device (during the study period) 8. Lymphocyte count (at the beginning of the study and during the study period) 9.Puls rate 10. COVID-19 incidence in prevention phase

## General information

**Reason for update**

Addition in prevention phase

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20200727048217N1**
Registration date: **2020-09-13, 1399/06/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-10, 1399/09/20**
Update count: **1**

**Registration date**

2020-09-13, 1399/06/23

**Registrant information**

**Name**

Moslem Jafarisani

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 23 3239 5054

**Email address**

moslem.jafarisani@shmu.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-08-22, 1399/06/01

**Expected recruitment end date**

2021-03-19, 1399/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Prophylaxis and treatment of COVID-19 using a nasal spray containing 3% dimethyl sulfoxide (DMSO) and 20% ethanol solution

**Public title**

Effect of ethanol and DMSO in prophylaxis and treatment of COVID-19

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

COVID-19 Patients Close contact with COVID-19 Patinets No current and previous infection with COVID-19 (for the preventive phase)

**Exclusion criteria:**

immigrant patients pregnant patients Anxiety and obsessive-compulsive disorder Protocol noncompliance

**Age**

From **20 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **610**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random allocation in SPSS software will be done using random quadruple blocks. Because patients are gradually admitted to the study and to block the sample size in the two groups, the block method of volume 4 is used. For this purpose, 6 quadruple blocks will be created as follows 1-AABB 2- ABAB 3-ABBA 4-BBAA 5-BABA 6-BAAB Where A is for treatment 1 and B is for treatment 2. The random order will be such that first a random number will be created in Excel from 0 to 9. Depending on which block the random number belongs to, the sequence of that block will be used to assign patients to the control and intervention groups. For example, if the random number generated is 6, the first person will be assigned to group B, the second person to group A, the third person to group A, and the fourth person to group B. To reach the calculated sample size, the random number creation will be repeated 110 times. Because each time the task is assigned, four diseases are identified. It should be noted that if the random number is 7, 8, 9 and 0, it will be ignored.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

This study will be done in triple blinds. placebo will be used for blinding, which is prepared in packages similar to the main intervention.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shahroud University of Medical Sciences

**Street address**

Hafte-tire square

**City**

Shahroud

**Province**

Semnan

**Postal code**

۳۶۱۴۷-۷۳۹۴۷

**Approval date**

2020-08-23, 1399/06/02

**Ethics committee reference number**

IR.SHMU.REC.1399.091

## Health conditions studied

### 1

**Description of health condition studied**

Covid-19

**ICD-10 code**

U07.1

**ICD-10 code description**

U07.1 COVID-19, virus identified

## Primary outcomes

### 1

**Description**

The mortality rate from Covid-19 patients

**Timepoint**

2 weeks after intervention

**Method of measurement**

Survived or died according to the records

### 2

**Description**

- Recovery rate from Covid-19

**Timepoint**

2 weeks after intervention

**Method of measurement**

qRT-PCR

**3**

**Description**

COVID-19 incidence in health employees

**Timepoint**

In intervention period

**Method of measurement**

qRT-PCR

## Secondary outcomes

**1**

**Description**

General Health

**Timepoint**

At the start and the end of study

**Method of measurement**

Check list according to the Likert scale

**2**

**Description**

O2 Saturation

**Timepoint**

Daily, 8,14 and 21 O'clock

**Method of measurement**

Pals Oxy-meter

**3**

**Description**

Respiratory Rate

**Timepoint**

Daily, 8,14 and 21 O'clock

**Method of measurement**

Physical examination and berth count

**4**

**Description**

Temperature

**Timepoint**

Daily, 8,14 and 21 O'clock

**Method of measurement**

Thermometer

**5**

**Description**

Length of hospitalization

**Timepoint**

At the end of study

**Method of measurement**

Date of hospitalization and discharge stated in the patient file

**6**

**Description**

The need for intensive care and respiratory support

**Timepoint**

At the end of study

**Method of measurement**

Date of transfer to the ICU and discharge stated in the patient file

**7**

**Description**

Time of separation from the ventilator

**Timepoint**

At the end of study

**Method of measurement**

Date stated in the patient file

**8**

**Description**

Lymphocyte

**Timepoint**

At the beginning and end of the study

**Method of measurement**

Cell counter

## Intervention groups

**1**

**Description**

Intervention group: patients will receive nasal spray containing 20% ethanol (German Merck), 3% dimethyl sulfoxide (German Merck) based on physiological serum. Three times a day (every 8 hours) a puff of spray will be applied to each nostril. The duration of use will be two weeks.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: patients will use a spray containing normal saline (Razi Iran). Three times a day (every 8 hours) a puff spray will be applied to each nostril. The duration of use will be two weeks.

**Category**

Placebo

**3**

**Description**

Intervention group: employees will receive nasal spray containing 20% ethanol (German Merck), 3% dimethyl sulfoxide (German Merck) based on physiological serum. Two times a day one puff of spray will be applied to each nostril. The duration of use will be 45 dayes.

**Category**

Prevention

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Imam Hossein hospital
**Full name of responsible person**
Moslem Jafarisani
**Street address**
Hafte-Tir square
**City**
Shahroud
**Province**
Semnan
**Postal code**
۳۶۱۴۷-۷۳۹۴۷
**Phone**
+98 23 3239 5054
**Fax**
+98 23 3239 5009
**Email**
moslem.jafarisani@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shahroud University of Medical Sciences
**Full name of responsible person**
Dr. Mohammad Hasan Emamian
**Street address**
7-e- Tir SQ
**City**
Shahroud
**Province**
Semnan
**Postal code**
۳۶۱۴۷۷۳۹۵۵
**Phone**
+98 23 3239 5054
**Fax**
+98 23 3239 5054
**Email**
vcr@shmu.ac.ir
**Web page address**
http://shmu.ac.ir/research/fa/page/689/%D9%85%D8%B9%D8%A7%D9%88%D9%86-%D8%AA%D8%AD%D9%82%DB%8C%D9%82%D8%A7%D8%AA-%D9%88-%D9%81%D9%86%D8%A7%D9%88%D8%B1%DB%8C
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shahroud 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**
Shahroud University of Medical Sciences
**Full name of responsible person**
Moslem Jafarisani
**Position**
Assiatant professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Biochemistry
**Street address**
Hafte Tir SQ
**City**
Shahroud
**Province**
Semnan
**Postal code**
۳۶۱۴۷۷۳۹۵۵
**Phone**
+98 21 8670 5503
**Fax**
+98 21 8670 5503
**Email**
moslem.jafarisani@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Shahroud University of Medical Sciences
**Full name of responsible person**
Moslem Jafarisani
**Position**
Assistant professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Biochemistry
**Street address**
Hafte Tir square
**City**
Shahroud
**Province**
Semnan
**Postal code**
۳۶۱۴۷۷۳۹۵۵
**Phone**

+98 23 3239 5054

**Fax**

+98 23 3239 5054

**Email**

moslem.jafarisani@shmu.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Moslem Jafarisani

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Biochemistry

**Street address**

Hafte Tir square

**City**

Shahroud

**Province**

Semnan

**Postal code**

۳۶۱۴۷۷۳۹۵۵

**Phone**

+98 23 3239 5054

**Fax**

+98 23 3239 5054

**Email**

moslem.jafarisani@shmu.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**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not 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**

Primary and secendry outcomes

**When the data will become available and for how long**

6 month after result publication

**To whom data/document is available**

Reserachers

**Under which criteria data/document could be used**

for citation

**From where data/document is obtainable**

SHMU Vice-Chancellor for Research and Technology - +982332396714

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

Send a requste form to SHMU Vice-Chancellor for Research and Technology

**Comments**