Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

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