Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Evaluation of trans sodium crocetinate spray against on mild to moderate ARDS induced by COVID-19 patients: A Randomized Open label Clinical Trial

Protocol summary

Study aim

Evaluation of trans sodium crocetinate spray in COVID-19 patients

Design

A randomized and open clinical trial with a parallel group design of 30 inpatients, randomizing with the table of random numbers.

Settings and conduct

This study will be performed on inpatients. In this study, 30 patients with covid-19 disease were selected and randomly assigned to two groups of 15 individuals. Patients in the standard diet control group will receive standard coronavirus treatment . In addition to the standard diet, patients in the treatment group will be treated with 1 mg/kg of trans sodium crocetinate i.v. for 1 week. Patients are monitored during 7 days hospitalization and daily checked for PF ratio, O2 saturation, vital signs as well as adverse drug reactions. At three days intervals, the function of liver, kidney and CBC will be checked. At the end of treatment, disease intensity parameters will be checked again in both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Patients with clinical diagnosis for Covid-19 disease, Patients with acute respiratory distress syndrome (ARDS), PF ratio (the ratio of arterial oxygen partial pressure to fractional inspired oxygen) <200 , Patients not having kidney, liver and heart dysfunction according to clinical and laboratory findings Exclusion criteria:Allergic reactions to saffron , pregnancy and breast-feeding, multi organ dysfunction disease

Intervention groups

The control group receives standard anti-coronavirus drugs . In addition to the common anticorona virus drugs, the treatment group also receives trans sodium crocetinate.

Main outcome variables

Primary outcomes: frequency of patients mortality Secondary outcomes:days under ventilation, hospitalization days in ICU, Getting multi organ dysfunction, improving PF ratio and sofa score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081019001369N7**
Registration date: **2020-09-27, 1399/07/06**
Registration timing: **prospective**

Last update: **2020-09-27, 1399/07/06**
Update count: **0**

Registration date

2020-09-27, 1399/07/06

Registrant information

Name

Hossein Hosseinzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3180 1193

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hosseinzadehh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of trans sodium crocetinate spray against on mild to moderate ARDS induced by COVID-19 patients: A Randomized Open label Clinical Trial

Public title

Clinical trial of trans sodium crocetinate against COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with clinical diagnosis for COVID-19 disease Patients with acute respiratory distress syndrome (ARDS) PF ratio (the ratio of arterial oxygen partial pressure to fractional inspired oxygen) <200 Patients not having kidney, liver and heart dysfunction according to clinical and laboratory findings

Exclusion criteria:

Allergic reactions to saffron Pregnancy and breast-feeding, Multi organ dysfunction disease

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization in three stages: 1- Random sequence generation: this step simple or limited randomization will be done based on a table of random numbers 2- Allocation concealment: which is done in the form of coded boxes (numbered drug containers) with a random sequence. In this method, a number of boxes with the same shape and size are numbered based on random sequences and contain drugs or placebo that have a completely similar appearance. 3- Execution of random allocation process: A: Identify the person who creates the random sequence B: A person who evaluates and registers researchers in terms of inclusion and exclusion criteria C: The person who assigned the participants to the groups: infectious diseases specialist The main researcher of the project, who creates a random sequence, does not interfere in other stages of randomization, including registration and allocation of participants, and the person involved in creating a random program is separate from other researchers.

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

Regional Ethics Committee of Mashhad University of Medical Sciences

Street address

Blv.Vakilabad 2- School of Pharmacy-1365-91775

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948954

Approval date

2020-09-12, 1399/06/22

Ethics committee reference number

IR.MUMS.REC.1399.414

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19 Disease

Primary outcomes

1

Description

Frequency of patients mortality

Timepoint

during 7 days hospitalization

Method of measurement

counting the number

Secondary outcomes

1

Description

days under ventilation

Timepoint

during 7 days hospitalization

Method of measurement
time

2

Description
hospitalization days in ICU
Timepoint
during 7 days hospitalization
Method of measurement
time

3

Description
Getting multi organ dysfunction
Timepoint
During 7 days hospitalization
Method of measurement
Clinical and laboratory evaluation

4

Description
Improving PF ration
Timepoint
daily during 7 days hospitalization
Method of measurement
ratio calculated from PaO2/FiO2

5

Description
Improving Sofa (The sequential organ failure assessment) score
Timepoint
the first day and during 7 days hospitalization
Method of measurement
According to clinical and laboratory evaluation

Intervention groups

1

Description
Intervention group: In addition to the standard treatment regimen for COVID-19, the trans sodium crocetinate spray with a nebulizer as an oral spray twice a day will be given for 1 week.
Category
Treatment - Drugs

2

Description
Control group: Patients will received the standard treatment regimen for COVID-19 for 7 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Zahra Javid Arabshahei
Street address
Imam Reza Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Daneshgah St
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9138813944
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Email
TafaghodiM@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Hossein Hosseinzadeh

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Clinical Pharmacy

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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
Not applicable