

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Feb 2021

### Evaluation of trans sodium crocetin 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 crocetin 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 crocetin i.v. for 1 week. Patients are monitored during 7 days hospitalization and daily checked for PF ratio, O<sub>2</sub> 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 crocetin.

##### 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

##### Email address

hosseinzadehh@mums.ac.ir

##### Recruitment status

**recruiting**

##### 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 crocetin 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 crocetin 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 crocetin 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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

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+98 51 3854 3031

**Email**

JavidAZ@mums.ac.ir

**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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Phone**

+98 51 3841 1538

**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

### Contact

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Mashhad University of Medical Sciences

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## Person responsible for scientific inquiries

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**Position**

Professor

**Latest degree**

Ph.D.

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**Fax**

## 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