

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Oct 2020

### Evaluation of the effect of trans sodium crocetinate in respiratory distress caused by COVID-19

#### Protocol summary

##### Study aim

Evaluation the effect of trans sodium crocetinate on acute respiratory distress syndrome in covid-19 patients

##### Design

A randomized and open controlled 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/day of trans O2 saturation, vital signs as well as adverse drug reactions. 2-On the first, third and seventh day, liver and kidney function tests and CBC will be checked. 3-At the end of treatment, the severity parameters of the disease are checked 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) <300; patients not having kidney, liver and heart dysfunction according to clinical and laboratory findings. Exclusion criteria: allergic reactions to saffron; pregnancy or 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 vials.

##### 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: **IRCT20081019001369N6**

Registration date: **2020-05-17, 1399/02/28**

Registration timing: **prospective**

Last update: **2020-05-17, 1399/02/28**

Update count: **0**

##### Registration date

2020-05-17, 1399/02/28

##### 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

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-21, 1399/04/01

##### Expected recruitment end date

2020-10-21, 1399/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of trans sodium crocetin in respiratory distress caused by COVID-19

## 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), Patients not having kidney, liver and heart dysfunction according to clinical and laboratory findings PF ratio (the ratio of arterial oxygen partial pressure to fractional inspired oxygen) <300 ,

### Exclusion criteria:

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

## Age

From **18 years** old to **65 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

Simple randomized method according to random numbers table

## 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

Medical Ethics Committee of Mashhad University of Medical Sciences

##### Street address

School of Pharmacy, Vakilabad 2- Blvd.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948954

## Approval date

2020-05-09, 1399/02/20

## Ethics committee reference number

IR.MUMS.REC.1399.245

## 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

Patients' mortality rate

#### Timepoint

During 7 days hospitalization

#### Method of measurement

Medical Reports

## Secondary outcomes

### 1

#### Description

Days under ventilation

#### Timepoint

During 7 days hospitalization

#### Method of measurement

Medical Reports

### 2

#### Description

Hospitalization days in ICU

#### Timepoint

During 7 days hospitalization

#### Method of measurement

Medical Report

### 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 PaO<sub>2</sub>/FiO<sub>2</sub>

## 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 1 mg/kg/day will be given i.v. for 1 weeks.  
**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**  
Amirhoushang Mohammadpour  
**Street address**  
Imam Reza Square  
**City**  
mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9137913316  
**Phone**  
+98 51 3180 1592  
**Email**  
MohamadpoorAH@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**  
Amirhoushang Mohammadpour  
**Position**  
Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Clinical Pharmacy  
**Street address**  
School of Pharmacy, Vakilabad 2 Blvd.  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9177948954  
**Phone**  
+98 51 3180 1592  
**Fax**  
+98 51 1882 3251  
**Email**  
MohamadpoorAH@mums.ac.ir

## Person responsible for scientific 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

**Street address**

School of Pharmacy, Vakilabad 2 Blvd.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948954

**Phone**

+98 51 3180 1193

**Fax**

+98 51 1882 3251

**Email**

hosseinzadehh@mums.ac.ir

## Person responsible for updating data

### 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

**Street address**

School of Pharmacy, Vakilabad 2 Blvd.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948954

**Phone**

+98 51 3180 1193

**Fax**

+98 51 1882 3251

**Email**

hosseinzadehh@mums.ac.ir

## 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