Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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)

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+98 51 3180 1193

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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 crocetinate in respiratory distress caused by COVID-19

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), 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 randome 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
Meedical Reports

Secondary outcomes

1

Description
Days under ventilation
Timepoint
During 7 days hospitalization
Method of measurement
Meedical 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 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 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

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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

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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

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Person responsible for scientific inquiries

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Position
Professor

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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