

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 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 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 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

Street address

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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

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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

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Hossein Hosseinzadeh

Position

Professor

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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