

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Feb 2023

Effect of Camostate mesylate on clinical improvement and outcome of Coronavirus (COVID-19)-induced pneumonia

Protocol summary

Study aim

Effect of Camostate mesylate on clinical improvement and outcome of patients with Coronavirus (COVID-19)-induced pneumonia will be studied.

Design

A clinical trial with a control group, with parallel groups, simple-randomly assigned to intervention and control groups, Phase 3, consisted of 40 patients

Settings and conduct

This study will be performed in Imam Reza Hospital, Tabriz, Iran. 40 patients will be divided into two groups (20 in each group) by simple randomization. The routine lab data, CT scan of lungs, hospitalization period, need to intubation and mortality rate will be assessed in both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with moderate to severe 2019-nCoV-infected patients; 18 Years to 80 Years; both genders and positive PCR will be involved in this study. Non-inclusion criteria: Patients with elevated liver enzymes (3 times); who are participating in other drug clinical trials; active pulmonary tuberculosis; definite bacterial and fungal infections; pregnant or lactating women.

Intervention groups

Intervention group: Patients in the Camostate mesylate group will be prescribed Camostate mesylate 200 mg three times daily for three days and standard regimen for COVID-19. Control group: patients in the control group will be prescribed the standard regimen for COVID-19.

Main outcome variables

The change of pneumonia severity on CT scan images; hospitalization period; mortality rate

General information

Reason for update

Acronym

ComCov

IRCT registration information

IRCT registration number: **IRCT20200317046797N1**
Registration date: **2020-04-03, 1399/01/15**
Registration timing: **prospective**

Last update: **2020-04-03, 1399/01/15**

Update count: **0**

Registration date

2020-04-03, 1399/01/15

Registrant information

Name

Sepideh Zununi Vahed

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 9331

Email address

sepide.zununi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-08, 1399/01/20

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Camostate mesylate on clinical improvement and outcome of Coronavirus (COVID-19)-induced pneumonia

Public title

Effect of Camostate mesylate on the outcome of Coronavirus (COVID-19)-induced pneumonia

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Moderate to severe 2019-nCoV-infected patients Being at the age of 18 to 80 years Patients or authorized family members volunteered to participate in this study and signed informed consent. Both genders pulmonary involvement in CT scan PCR positive

Exclusion criteria:

Patient with elevated liver enzymes 3 time the upper limit of normal Patients who are participating in other drug clinical trials Patients with active pulmonary tuberculosis Patients with definite bacterial and fungal infections Pregnant or lactating women Patient with active thrombotic event

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization sequence will be generated with a computer from 1 to 40. The computer will divide the digits between the two groups. According to the sequence of admission, the patients will be allocated to the control or the Camostate mesylate groups regarding the sequence of computerized random list.

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**

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2020-03-17, 1398/12/27

Ethics committee reference number

IR.TBZMED.REC.1398.1312

Health conditions studied**1****Description of health condition studied**

Coronavirus (COVID-19)-induced pneumonia

ICD-10 code

J12.89

ICD-10 code description

Other viral pneumonia

2**Description of health condition studied**

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes**1****Description**

Lung symptoms

Timepoint

At baseline (before intervention) and after drug administration

Method of measurement

Lung CT scan

2**Description**

Hospitalization period

Timepoint

At baseline and discharge time

Method of measurement

Counting the day

3**Description**

Mortality rate

Timepoint

At baseline and discharge time

Method of measurement

Observation

4

Description

Need for intubation

Timepoint

At baseline and discharge time

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Twenty patients with Coronavirus (COVID-19)-induced pneumonia in addition to standard regimen of covid-19, will receive Camostate mesylate tablets for 3 days (200 mg three times daily).

Category

Treatment - Drugs

2

Description

Control group: they will receive standard regimen for COVID-19 patients.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Imam Reza Hospital

Full name of responsible person

Dr Khalil Ansarin

Street address

Imam Reza Hospital; Golgasht street

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Tabriz

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5166614766

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Email

dr.ansarin@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Mohammad Samiei

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Third Floor; Central Building # 2; Tabriz University of Medical Sciences; Golgasht street

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Samiei.moh@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Khalil Ansarin

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Mohammad Reza Ardalan

Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Sepideh Zununi Vahed

Position

Assistant Prof.

Latest degree

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Other areas of specialty/work

Medical Biotechnology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Considering the crisis conditions of the Pandemic Corona and the increasing number of patients, our top priorities are the patients management and the search for effective medication (s).

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable