

# 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

###### **City**

Tabriz

###### **Province**

East Azarbaijan

###### **Postal code**

5166614766

###### **Phone**

+98 41 3335 2073

###### **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

##### **Street address**

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

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5166614766

##### **Phone**

+98 41 3335 7310

##### **Email**

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**

Internal Medicine

###### **Street address**

Imam Reza Hospital; Golgasht street

###### **City**

Tabriz

###### **Province**

East Azarbaijan

###### **Postal code**

5166616471

###### **Phone**

+98 41 3335 2898

###### **Email**

dr.ansarin@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mohammad Reza Ardalan

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Golgasht street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Phone**

+98 41 3336 9331

**Email**

ardalan34@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Sepideh Zununi Vahed

**Position**

Assistant Prof.

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Biotechnology

**Street address**

Tabriz University of Medical Sciences; Golgasht Street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Phone**

+98 41 3336 9331

**Email**

sepide.zununi@gmail.com

## 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