Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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)
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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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5166614766
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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

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Position
Professor

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Other areas of specialty/work
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Person responsible for updating data

Contact

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Sepideh Zununi Vahed

Position
Assistant Prof.

Latest degree
Ph.D.

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