Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of efficacy and safety of Glurunic acid (G2013) in patients with COVID-19

Protocol summary

Study aim
Investigating efficacy and safety of Gluronic acid capsule in patients with moderate to severe COVID-19
Design
a multi-center, randomized, open-labeled, controlled, parallel phase 3 clinical trial
Settings and conduct
Patients who will admitted to Chamran, Baqiyatallah or Farhikhtegan hospital and will meet the inclusion criteria, will be entered to the study, and will randomly assigned into two groups of intervention and control.
Participants/Inclusion and exclusion criteria
Inclusion criteria:confirmed diagnosis of COVID-19; the written consciously and freely consent to participate in the study; moderate to severe Corona-Virus associated pneumonia; in the first 48 hours after his/her inclusion, there is no possibility of discharge from hospital.
Exclusion criteria: Pregnancy; Lactation; The patient is involved at another clinical trial at the same time; Severe renal impairment; Severe hepatic impairment; Severe heart failure; uncontrolled diabetes; active infection; active cancer; coagolupathy; primary immunodeficiency syndrome.
Intervention groups
Capsule Gluronic acid 500mg, 2 capsule every 12 hours, after meal, for 4 weeks; in addition to routine treatment according to the latest national guideline.
Main outcome variables
Need to receive ICU service rate

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20080901001165N64**
Registration date: **2021-05-21, 1400/02/31**
Registration timing: **prospective**
Last update: **2021-05-21, 1400/02/31**
Update count: **0**
Registration date
2021-05-21, 1400/02/31

Registrant information
Name
Yunes Panahi
Name of organization / entity
Baqiyatallah University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-05-31, 1400/03/10
Expected recruitment end date
2021-09-01, 1400/06/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of efficacy and safety of Glurunic acid (G2013) in patients with COVID-19

Public title
Evaluation of efficacy and safety of Glurunic acid (G2013) in patients with COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria

Inclusion criteria:
Confirmed diagnosis of COVID-19, with either lung CT-Scan result, which is typical for COVID-19 pulmonary involvement,or RT-PCR confirmation. The patient/Legal guardian has written consciously and freely consent to participate in the study; In the first 48 hours after his/her inclusion into this study, there is no possibility of discharge from the patient's hospital; Moderate to severe COVID pneumonia
Exclusion criteria:
Pregnancy Lactation The patient is present at another clinical trial at the same time. Severe renal impairment Severe hepatic impairment Severe cardiac impairment Uncontrolled diabetes Active infection Active cancer Coagulopathy Primary immunodeficiency syndrome Allergy to Glurunic acid

Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **180**
Randomization (investigator's opinion)
Randomized
Randomization description
Block Randomization method is used to randomized the patients. For randomization, we visited the www.sealedenvelope.com, then randomization tab and make a list option were selected, the number of intervention groups, sample size, block size (which was selected due to the small sample size, 4)were entered the intended locations, then a random list containing the pattern of patient allocation was obtained in two intervention.
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 Shahid Chamran Hospital
Street address
Shahid Chamran hospital, Sanaaye St., Shahid Langari St., Nobonyad Sq., Pasdaran Ave., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1913913455
Approval date
2021-03-02, 1399/12/12
Ethics committee reference number
IR.CHAMRANHOSPITAL.REC.1399.003

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
Covid-19

Primary outcomes

1

Description
Need to receive ICU service rate (occurrence of shock, resistant hypoxemia despite receiving oxygen via reservoir oxygen mask, GCS score drops below 12)
Timepoint
Daily
Method of measurement
Clinical assessment

Secondary outcomes

1

Description
Mortality rate
Timepoint
30 days after including the study
Method of measurement
Clinical assessment

2

Description
Length of hospitalization
Timepoint
The first day and the end of hospitalization
Method of measurement
The hospital record review

3

Description
Laboratory changes
Timepoint
Daily until discharge
Method of measurement

Blood sample, laboratory analysis

4

Description
Fever
Timepoint
Daily until discharge
Method of measurement
Clinical assessment

5

Description
Respiratory distress
Timepoint
Daily until discharge
Method of measurement
Clinical assessment

6

Description
Oxygen saturation without receiving oxygen supplement
Timepoint
Daily until discharge
Method of measurement
Pulse-oxymetery device

7

Description
Side effects
Timepoint
Daily during hospitalization, weekly after discharge
Method of measurement
During hospitalization by clinical evaluation, after discharge by telephone follow-up

Intervention groups

1

Description
Intervention group: Guluronic acid (G2013) capsule 500 mg, 2 capsules every 12 hours, after meal, for 4 weeks; in addition to routine treatment according to the latest national guideline.
Category
Treatment - Drugs

2

Description
Control group: routine treatment according to the latest national guideline.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah hospital
Full name of responsible person
Yunes Panahi
Street address
Baqiyatallah hospital, Mollasadra St., Vanak
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2

Recruitment center
Name of recruitment center
Shahid Dr. Chamran hospital
Full name of responsible person
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3

Recruitment center
Name of recruitment center
Farhikhtegan hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ministry of Defense, Department of Health
Full name of responsible person
Reza Allah-varn
Street address
Sanaaye St., Shahid-Langari St., No-bonyad Sq., Pasdaran Ave.
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Email
name@domian.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ministry of Defense, Department of Health
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Dr. Chamran hospital
Full name of responsible person
Armita Mahdavi Goorabi
Position
Ph.D
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Mulecular medicine
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Person responsible for scientific inquiries

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Person responsible for updating data

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Specialist
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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
Undecided - It is not yet known if there will be a plan to make this available