

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

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

Protocol summary

Study aim

Investigating efficacy and safety of Glurunic 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; coagulopathy; primary immunodeficiency syndrome.

Intervention groups

Capsule Glurunic 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

Country

Iran (Islamic Republic of)

Phone

+98 21 8821 1524

Email address

yunespanahi@bmsu.ac.ir

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 Gluronic 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-oxymetry 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: Gyluronic 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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1435916471

Phone

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Email

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2

Recruitment center

Name of recruitment center

Shahid Dr. Chamran hospital

Full name of responsible person

Hamideh Khazraeiyan

Street address

Sanaaye St., Shahid Langari St., Nobonyad Sq.,
Pasdaran Ave.

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Fax

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3

Recruitment center

Name of recruitment center

Farhikhtegan hospital

Full name of responsible person

Hamidreza Gholamrezaei

Street address

Shohadaye Hesarak Blvd, Hesarak

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1477899679

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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

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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

Latest degree

Ph.D.

Other areas of specialty/work

Molecular medicine

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Yunes Panahi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Critical care pharmacotherapy

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Person responsible for updating data

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Parisa Kianpour

Position

Specialist

Latest degree

Specialist

Other areas of specialty/work

Critical care pharmacotherapy

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parisa_kianpour@yahoo.com

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