Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluation of the efficacy and safety of Rabbit polyclonal antibody (CoviGlobulin) in patients with coronavirus COVID-19 virus moderate to severe

Protocol summary

Study aim
Evaluation of the efficacy and safety of using rabbit polyclonal antibodies in the treatment of patients with severe covid 19 infection (COVID-19)

Design
Clinical evaluation has a parallel, unblinded, randomized control group

Settings and conduct
The study is being conducted in Tehran and at Baqiyatallah Al-Azam Hospital.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patient over 18 years of age, signature form of conscious consent to participate in the study by himself or the patient's guardian, patient with moderate to severe Severe disease. Non-inclusion criteria: People with a history of allergies to blood products such as IVIG or albumin. The patient has critical conditions such as multiple organ failure. pregnant women. Breastfeeding mothers. The patient is receiving treatment and medication outside the standard COVID 19 treatment protocol, and the physician believes that the patient is not suitable to participate in this trial. Known sensitivity to rabbit proteins

Intervention groups
CoviGlobulin (rabbit polyclonal antibody) drug candidate: Receive CoviGlobulin r at a dose of 1-3 mg per kg body weight (1-3 mg / kg / d) for 2–4 days 2) Receive basic COVID-19 treatment based on the protocol approved by the Ministry of Health control group : 1) Receive basic COVID-19 treatment based on the protocol approved by the Ministry of Health

Main outcome variables
1- Clinical improvement within 14 days after patient admission 2- The mortality of patients within 14 days is determined on a daily basis and based on examination and clinical history.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200508047346N1**
Registration date: **2020-05-13, 1399/02/24**
Registration timing: **prospective**

Last update: **2020-05-13, 1399/02/24**
Update count: **0**

Registration date
2020-05-13, 1399/02/24

Registrant information

Name
Mahdi Behdani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 6411 2144

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behdani73042@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-21, 1399/03/01

Expected recruitment end date
2021-03-19, 1399/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy and safety of Rabbit polyclonal antibody (CoviGlobulin) in patients with coronavirus COVID-19 virus moderate to severe

Public title
Evaluation of the effectiveness of rabbit antibody against coronavirus in patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Based on clinical and laboratory symptoms, the person has been confirmed to have COVID-19. The patient is over 18 years old The patient is hospitalized and shows one of the moderate to severe clinical symptoms of COVID-19, including the following: Severe clinical symptoms: Having any of the following: shortness of breath, respiratory rate more than 30 times per minute , Oxygen saturation of blood less than 93% (at rest), ratio of arterial oxygen pressure to inhaled oxygen less than 300, pulmonary infiltration more than 50% over 24 to 48 hours. Volunteer to participate in the study and sign a conscious consent form for yourself or your legal guardian. Admission of patients is random and grouped to participate in the study (control or treatment group). The patient is hospitalized before the end of the clinical study and is available for any further evaluation

Exclusion criteria:
People with a history of allergies to blood products such as IVIG or albumin. The patient has critical conditions such as multiple organ failure. pregnant women. Breastfeeding mothers. The patient is receiving treatment and medication outside the standard COVID 19 treatment protocol, and the physician believes that the patient is not suitable to participate in this trial. Known sensitivity to rabbit proteins

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **124**

Randomization (investigator's opinion)
Randomized

Randomization description
Making a random number sequence of patients is done online by the sealed envelop site. Using randomly placed blocks, blocks (the size of each block is 4) will be made for a total of 124 patients.

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
Baqiyatallah University of Medical Sciences

Street address
Mulla Sadar, Sheikh Baha'i, Baqiyatallah Al-Azam Hospital

City
Tehran

Province
Tehran

Postal code
1435915371

Approval date
2020-04-19, 1399/01/31

Ethics committee reference number
IR.BMSU.REC.1399.110

Health conditions studied

1

Description of health condition studied
Emerging pneumonia caused by the covid virus 19

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Clinical improvement within 14 days after patient admission

Timepoint
every day

Method of measurement
2-point decrease in the patient's level compared to the admission time level. 6-point scale includes: score 6: death score 5: hospitalization for ECMO and (or) mechanical ventilation score 4: non-invasive ventilation or high-current oxygen therapy score 3: hospitalization for oxygen therapy (not high current and mechanical ventilation) Not required) Score 2: Hospitalization Score 1: Clearance

2

Description
Patient mortality rate in 14 days

Timepoint
every day

Method of measurement

Clinical observation

Secondary outcomes

1

Description
Hospitalization Duration
Timepoint
Patient discharge day
Method of measurement
Examination and history

2

Description
ICU Hospitalization Duration
Timepoint
everyday
Method of measurement
Examination and history

3

Description
Invasive mechanical ventilation
Timepoint
every day
Method of measurement
Examination and history

4

Description
ECMO duration
Timepoint
every day
Method of measurement
Examination and history

5

Description
Proportion of PCR negative (3 AND 7 days after transfusion)
Timepoint
3 days and 7 days after injection
Method of measurement
PCR

6

Description
Clinical characteristics including, Fever, Respiratory frequency(RF) and PaO2/FiO2
Timepoint
every day
Method of measurement
Examination and history

Intervention groups

1

Description
The intervention group includes patients with moderate to severe COVID-19 symptoms who have been diagnosed with coronavirus by PCR: (1) CoviGlobulin (rabbit polyclonal antibody) intake of 1-3 mg per kg body weight Body (1-3 mg / kg / d) for 2-4 days. (2) Receive the basic COVID-19 treatment based on the protocol approved by the Ministry of Health
Category
Treatment - Other

2

Description
Control group: Receive basic COVID-19 treatment based on protocol approved by the Ministry of Health
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah Al-Azam Hospital
Full name of responsible person
Dr. Mostafa Ghanei
Street address
18/5000 Mulla Sadra, Sheikh Baha'i
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1435915371
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kowsar Biotechnology Co.
Full name of responsible person
Sirous Zeinali
Street address
No. 41, Kosar Complex, 3rd Floor, Majlesi St., Valiasr St., Above Fatemi St., Tehran, Tehran
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1595645513
Phone

+98 21 8893 9150

Email

kbc@kawsar.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kowsar Biotechnology Co.

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Kowsar Biotechnology Company

Full name of responsible person

Sirous Zeinali

Position

CEO

Latest degree

Ph.D.

Other areas of specialty/work

Medical Genetics

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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

Mostafa Ghanei

Position

full Profesor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After the publication of the article, confidential information such as patient and hospital details, etc. will be deleted and other information will be provided to

researchers.

When the data will become available and for how long

After publishing the article

To whom data/document is available

Medical professionals

Under which criteria data/document could be used

Medical professionals can access data for research purposes

From where data/document is obtainable

Refer to the email of the responsible author

What processes are involved for a request to access data/document

Official and academic email to the responsible author

Comments