

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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)

##### Phone

+98 21 6411 2144

##### Email address

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 PaO<sub>2</sub>/FiO<sub>2</sub>

#### 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

##### City

Tehran

##### Province

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##### Postal code

1435915371

##### Phone

+98 21 81261

##### Email

mghaneister@gmail.com

## 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

##### City

Tehran

##### Province

Tehran

##### Postal code

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

**Street address**

No. 41, Kosar Complex, 3rd Floor, Majlesi St., Valiasr St., Above Fatemi St., Tehran, Tehran

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zeinali@gmail.com

## 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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## Person responsible for updating data

**Contact**

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**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Biotechnology

**Street address**

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**Email**

behdani73042@yahoo.com

## 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**