

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation of the effectiveness of intravenous infusion of human COVID-19 hyperimmune plasma with specific antibody titer in hospitalized patients with Covid-19: a randomized clinical trial

Protocol summary

Study aim

Evaluation of the effectiveness of intravenous infusion of human COVID-19 hyperimmune plasma with specific antibody titer in hospitalized patients with Covid-19: a randomized clinical trial

Design

Case-control, 3 arm, parallel, single center, phase 3 clinical trial

Settings and conduct

This study will be performed in the lung diseases ward of Imam Khomeini Hospital in Tehran. Eligible patients with free and informed written consent will randomly assigned to one of the study groups and receive the relevant intervention.

Participants/Inclusion and exclusion criteria

Confirmed or suspected COVID-19 pneumonia based on PCR or pulmonary imaging; Presenting clinical symptoms of COVID-19 (fever, cough, dyspnea); O2 saturation equal or less than 93%; Age equal or more than 18 years old; The patient has informed and free written consent to participate in the study; Less than 7 days passed from the onset of clinical symptoms to the time of enrollment; The patient should not attend another clinical trial at the same time.

Intervention groups

Arm1: Human COVID-19 hyperimmune plasma with a specific antibody titer, volume 500ml, intravenous infusion over 4 hours; In addition to routine treatment based on the latest update of the national protocol. Arm2: Routine Human COVID-19 hyperimmune plasma, volume 500ml, intravenous infusion over 4 hours; In addition to routine treatment based on the latest update of the national protocol. Arm3: Routine treatment based on the latest update of the national protocol.

Main outcome variables

Requirement of receiving ICU care, mortality rate, requirement of mechanical ventilation, length of

hospitalization, NEWS2 score changes, Ordinal Scale changes, chest ct-scan score changes, side effects.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201004048922N1**

Registration date: **2020-10-10, 1399/07/19**

Registration timing: **prospective**

Last update: **2020-10-10, 1399/07/19**

Update count: **0**

Registration date

2020-10-10, 1399/07/19

Registrant information

Name

Hamidreza Abtahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2796

Email address

hrabtahi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-11, 1399/07/20

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of intravenous infusion of human COVID-19 hyperimmune plasma with specific antibody titer in hospitalized patients with Covid-19: a randomized clinical trial

Public title
Evaluation of the effectiveness of intravenous infusion of human COVID-19 hyperimmune plasma with specific antibody titer in hospitalized patients with Covid-19: a randomized clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed or suspected COVID-19 pneumonia based on PCR or pulmonary imaging; Presenting clinical symptoms of COVID-19 (fever, cough, dyspnea); O2 saturation equal or less than 93%; Age equal or more than 18 years old; The patient has informed and free written consent to participate in the study; Less than 7 days passed from the onset of clinical symptoms to the time of enrollment; The patient should not attend another clinical trial at the same time.

Exclusion criteria:
Advanced renal or liver disease; Active cancer; Known Hypersensitivity reaction to Plasma-derived drugs; Pregnancy; Lactation; The patient may be excluded from the study during the first 48 hours.

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the Block Randomization method will be used. To perform, by visiting the site www.sealedenvelope.com, while entering the number of intervention groups, sample size, block size (which was selected according to the number of study groups, 6), a random list of patients in 3 groups will be obtained that this list will be used for random allocation of 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

Ethics committee of Tehran University of Medical Sciences

Street address

Building No. 1 of the School of Medicine, Poursina St. North Door of the University, Ghods St., Enghelab Ave.

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2020-09-09, 1399/06/19

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.436

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

Length of hospital stay due to covid-19

Timepoint

Daily until discharge or death

Method of measurement

Count the days of hospitalization from the time of admission to the hospital until discharge or death

Secondary outcomes

1

Description

Mortality rate on day 28

Timepoint

Day 28 from enrollment

Method of measurement

Clinical assessment

2

Description

Requirement rate of mechanical ventilation

Timepoint

day 1 to 7

Method of measurement

Clinical assessment

3

Description

Requirement rate of receiving ICU care

Timepoint

Day 1 to 7

Method of measurement

Clinical assessment

4

Description

The 7-point ordinal scale

Timepoint

Day 1 and 7

Method of measurement

Clinical assessment

5

Description

National Early Warning Score 2 (NEWS2) changes

Timepoint

Day 1 and 7

Method of measurement

Clinical assessment and laboratory findings

6

Description

Chest CT-scan score changes

Timepoint

Day 1 and 28

Method of measurement

Chest CT scan

7

Description

Side effects

Timepoint

Day 1 to 7

Method of measurement

Clinical assessment

Intervention groups

1

Description

Intervention group: Human COVID-19 hyperimmune plasma with a specific antibody titer, volume 500ml, intravenous infusion over 4 hours; In addition to routine treatment based on the latest update of the national

protocol.

Category

Treatment - Drugs

2

Description

Intervention group: Routine Human COVID-19 hyperimmune plasma, volume 500ml, intravenous infusion over 4 hours; In addition to routine treatment based on the latest update of the national protocol.

Category

Treatment - Drugs

3

Description

Control group: Routine treatment based on the latest update of the national protocol.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini Complex hospital

Full name of responsible person

Mohammadreza Salehi

Street address

Dr.Gharib St, End of Keshavrz Blvd.

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Phone

+98 21 6693 9001

Email

salehi.mohamad3@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammadali Sahraeiyan

Street address

6th floor, University Central Organization, corner of Quds St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3698

Email

vcr@tums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Hamidreza Abtahi

Position

Associated Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pulmonary disease

Street address

Imam Khoemini Complex hospital, Dr.Gharib St., End of Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6693 9001

Email

hrabtahi@sina.tums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Hamidreza Abtahi

Position

Associated Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pulmonary disease

Street address

Imam Khomeini Complex hospital, Dr.Gharib St., End of Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6693 9001

Email

hrabtahi@sina.tums.ac.ir

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

Pharmacotherapy

Street address

Pharmacy faculty, Tehran University of Medical Science, 16 Azar St., Enghelab Ave.

City

Tehran

Province

Tehran

Postal code

1417614411

Phone

+98 21 6695 4709

Email

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