Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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
Pharmacotherpay
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