

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Comparison of The Therapeutic Effect of Convalescent Plasma and Plasma-derived Immunoglobulin-enriched solution on COVID-19 Patients: A Clinical Trial Study

Protocol summary

Study aim

Evaluating the therapeutic effect of Convalescent Plasma and Plasma-derived Immunoglobulin-enriched solution on COVID-19 Patients

Design

A hospital-based, parallel-group, single-blind, and randomized controlled trial

Settings and conduct

_COVID-19 patients (2 subgroups) & Controls: _Patients will treat with IV convalescent plasma and or plasma-derived immunoglobulin-enriched solution (PDIES), respectively. _PDIES will produce by an improved Cohn method. _Assessment of the patients' clinical and paraclinical improvement.

Participants/Inclusion and exclusion criteria

_Inclusion criteria for the intervention groups:1- COVID-19 Patients who have specified COVID-19 clinical symptoms, the positive RT-qPCR test result, positive CT scan, and informed consent; and those who do not respond to routine treatments or are in critical condition. _Inclusion criteria for Plasma donors: patients who meet all of the following characteristics: 1- Individuals with a recovery period longer than one week after discharge, 2- negative RT-qPCR test result, 3- age ranged 20-45 years old, 4- Individuals who their tests result for Hepatitis B, C, AIDS, syphilis, HTLV-1, and influenza is 100% negative. _Exclusion criteria:1. Pregnant and Lactating Women, 2. Patients with/or with a history of dangerous underlying diseases 4, Individuals who exhibit specific allergic reactions to intravenous administration. 5. Smokers

Intervention groups

Intervention group 1 & 2: Suspected COVID-19 Patients who meet all of the following characteristics: 1- Patients with clinical signs of COVID-19 2- The positive CT scan 3- A Positive RT-PCR Test Result 4- Patients who do not respond to routine treatment or are in critical condition.

5- Informed Consent

Main outcome variables

Complete remission of clinical signs The negative qRT-PCR test Improved CT scan Normal levels of biomarkers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200310046736N1**

Registration date: **2020-04-01, 1399/01/13**

Registration timing: **prospective**

Last update: **2020-04-01, 1399/01/13**

Update count: **0**

Registration date

2020-04-01, 1399/01/13

Registrant information

Name

Parastoo Moradi Choghakabodi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3337 7435

Email address

parastoomoradi40@yahoo.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2641-06-14, 2020/03/24

Expected recruitment end date

2641-10-16, 2020/07/24

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of The Therapeutic Effect of Convalescent Plasma and Plasma-derived Immunoglobulin-enriched solution on COVID-19 Patients: A Clinical Trial Study

Public title
Comparison of The Therapeutic Effect of Convalescent Plasma and Plasma-derived Immunoglobulin-enriched solution on COVID-19 Patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

COVID-19 Patients who have the clinical signs of COVID-19 infection such as fever, cough, sputum production, sore throat, and so on. Patients with the positive CT scan Patients who declare Informed Consent for this study.

Exclusion criteria:

Pregnant Women (based on WHO protocol) Lactating Women (based on WHO protocol) Individuals who exhibit specific allergic reactions to intravenous administration. Patients with/or with a history of dangerous underlying diseases such as IgA deficiency Patients with/or with a history of dangerous diseases such as cardiovascular and or hematological disorders (hemophilia, thalassemia, leukemia). Patients with/or with a history of underlying diseases such as liver and kidney disease Smokers

Age
From **20 years** old to **45 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
simple randomization with a random digit table

Blinding (investigator's opinion)
Single blinded

Blinding description
_ Participants are blinded to the details of the treatment process. _ Investigators (including Outcome assessor and Data analyzer) are blinded to knowing who is being given the treatment and who is not, and only receive the Patient's data and lab results from a physician as three subgroups A & B & C. But they don't know which are

controls and or intervention groups! _ The care provider (an expert physician) will randomly divide patients into 2 groups [controls, and 2 subgroups], and then do the intervention treatment. Only he knows which subgroup belongs to controls, or intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of University Research, Ahvaz Jundishapur University of Medical Sciences, School of

Street address

Ahvaz Jundishapur University of Medical Sciences, School of Medicine, Department of Emergency Medicine

City

Ahvaz

Province

Khuzestan

Postal code

1931070806

Approval date

2020-03-24, 1399/01/05

Ethics committee reference number

IR.AJUMS.REC.1399.003

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

B97.29

ICD-10 code description

Other coronavirus as the cause of diseases classified elsewhere

Primary outcomes

1

Description

Primary outcome: complete remission of clinical signs of disease

Timepoint

About one week after starting the treatment

Method of measurement

Clinical and laboratory questionnaire

2

Description

Negative result for COVID-19 RT-PCR test

Timepoint

About 7-14 days after starting the treatment

Method of measurement

Results of qRT-PCR test

3

Description

Normal CT Scan

Timepoint

About 7-14 days after starting the treatment

Method of measurement

Result of CT scan.

Secondary outcomes

1

Description

Recovery and normal levels of biomarkers associated COVID-19

Timepoint

At least 1 to 2 weeks after treatment

Method of measurement

Laboratory Techniques

Intervention groups

1

Description

In this intervention group COVID-19 patients who do not reply to routine treatments and are in a critical stage and prolonged hospitalization will be treated with convalescent plasma (obtained from fully recovered patients according to inclusion criteria) {200 cc/day intravenous (IV) administration for 1 to 4 hours} for 1-4 days.

Category

Treatment - Drugs

2

Description

The second intervention group will be treated with Plasma-derived Immunoglobulin-enriched solution {IV, 0.2 _0.4 g/kg/day based on the patient's physiological tolerance}.

Category

Treatment - Drugs

3

Description

The control group will only receive routine care without any new therapeutic interventions.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital of Ahvaz; Blood Transfusion Organization of Khuzestan, Ahvaz

Full name of responsible person

Mandana Puladzadeh

Street address

Razi Hospital of Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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Grant name

Faculty Research Grants (FRGs)

Grant code / Reference number

IR.AJUMS.REC.1399.003

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

Yes

Title of funding source

Ahvaz 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

2

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi

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Ahvaz Jundishapur University of Medical Sciences,
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Ahvaz University of Medical Sciences
Proportion provided by this source
50

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
Ahvaz University of Medical Sciences
Full name of responsible person
Mandana Puladzadeh
Position
Emergency medicine specialist
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine

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Person responsible for updating data

Contact

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Parastoo Moradi Choghakabodi
Position
MD Clinical Researcher
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Medical doctor
Other areas of specialty/work
Infectious diseases; Malignant hematological diseases; Cancers

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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

Clinical, Laboratory, and Demographic Data of COVID-19 Patients undergoing Convalescent Plasma Therapy and or Immunoglobulin therapy

When the data will become available and for how long

About 5 to 8 months after starting the study

To whom data/document is available

Public

Under which criteria data/document could be used

Detailed study information can be provided to competent researchers interested in designing immunological vaccines.

From where data/document is obtainable

Corresponding Author

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

Competent & enthusiastic researchers can receive detailed data from the corresponding author after the publication of work and by providing their identifiable information.

Comments

This Clinical Trial with the title of "Comparison of The Therapeutic Effect of Convalescent Plasma and Plasma-derived Immunoglobulin-enriched solution on COVID-19 Patients: A Clinical Trial Study" has not been previously registered and is not being concurrently submitted elsewhere. We are very pleased to register our Clinical Trial on the IRCT website (www.irct.ir). Thank you for your time and kindness. Best Health & Moments