Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 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- COVIDE-19 Patients who have specified COVIDE-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

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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 COVIDE-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

Khouzestan

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

COVIDE-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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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, School of Medicine, Golestan Blv. Esfand Ave, Ahvaz, Iran.
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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
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Person responsible for updating data

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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