Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 2020

Immediate uses of convalescent covid-19 plasma in the treatment of new infected patients at the first day of hospitalization in a clinical trail

Protocol summary

Study aim

The purpose of this study is immediate uses of convalescent covid-19 plasma in the treatment of new infected patients at the first day of hospitalization in a clinical trail and evaluate the effectiveness of this type of treatment.

Design

Clinical trials have a control group, with parallel groups and phase 3 on 100 patients. The case group are 50 patients. The control group are 50 patients who are either not in randomization or not satisfied with receiving plasma.

Settings and conduct

The study is being conducted in Khuzestan province: Ahvaz, Razi Hospital and in Sistan and Baluchestan province: Zahedan, Bouali Hospital. After being hospitalized by the treating physician in hospital, treatment begins with the diagnosis and judgment of Covid-19. In the case group, plasma injection will be one of the first hospital treatment orders.

Participants/Inclusion and exclusion criteria

Symptomatic COVID-19 patients who are hospitalized and have Score>4 in terms of WHO Progression Scale will enter the study. COVID-19 patients who have Score<4 in terms of WHO Progression Scale and more than 24 hours passed from the hospitalization, wont enter the study.

Intervention groups

Convalescent plasma injection, a 500 cc unit will be injected to the case group within 4 hours in addition to antiviral and treatments available at the hospital. The control group treatment will only be antiviral and inpatient care.

Main outcome variables

The rate of reduction in the duration of hospital stay of patients; mortality reduction; requirement of artificial ventilation and entry into the ICU; The rate of achieve to minimum 2 point decrease in WHO clinical scale since plasma usage OR WHO score less than 3 (each achieved first)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200525047562N1**
Registration date: **2020-06-14, 1399/03/25**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-24, 1399/04/04**
Update count: **1**

Registration date

2020-06-14, 1399/03/25

Registrant information

Name

Peyman Eshghi

Name of organization / entity

High institute for research & education in transfusion medicine

Country

Iran (Islamic Republic of)

Phone

+98 21 8860 1582

Email address

p.eshghi@ibto.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-25, 1399/03/05

Expected recruitment end date

2020-07-26, 1399/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Immediate uses of convalescent covid-19 plasma in the treatment of new infected patients at the first day of hospitalization in a clinical trail

Public title

Treatment of Covid-19 patients with convalescent plasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Symptomatic COVID-19 patients who are hospitalized and have Score>4 in terms of WHO Progression Scale. The least reasons of hospitalization are dyspnea and/or SPO2<93% or RR>30 The intervention should be performed within the first 24 hours of hospitalization.

Exclusion criteria:

COVID-19 patients having Score<4 in terms of WHO Progression Scale. More than 24 hours passed from hospitalization.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 the High Educational and Research Institute of Transfusion Medicine

Street address

High Educational and Research Institute of Transfusion Medicine, Shahid Hemmat HWY at Sheikh Fazlollah Nouri HWY, next to Milad Tower

City

Tehran

Province

Tehran

Postal code

1449613111

Approval date

2020-05-20, 1399/02/31

Ethics committee reference number

IR.TMI.REC.1399.003

Health conditions studied

1

Description of health condition studied

COVID-19 disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Reduce at least 2 points on clinical signs or score less than 3, each earlier.

Timepoint

At the beginning of the study (before the start of the intervention) and day 4 of hospitalization, day 7 of hospitalization and discharge time.

Method of measurement

WHO Progression Scale

2

Description

length of hospital stay

Timepoint

Hospitalization time to discharge

Method of measurement

Counting days

Secondary outcomes

1

Description

The rate of need for artificial ventilation and entry into the ICU

Timepoint

From hospitalization to discharge

Method of measurement

Percentage calculation

Intervention groups

1

Description

Intervention group: Symptomatic COVID-19 patients who are hospitalized and have Score>4 in terms of WHO Progression Scale. Before 24 hours passed from the hospitalization. A 500 cc unit with blood group compatibility between receiver and donor is injected within 4 hours. In patients with grade 7 and above, a plasma unit can be re-injected after 24 hours. Plasma is obtained by apheresis from patients who have recovered from the covid-19 virus in blood transfusion centers.

Category

Treatment - Drugs

2

Description

Control group: The control group is a patient who is hospitalized with suspicion of Covid-19 but either not in randomization or not satisfied with receiving plasma.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Hospital

Full name of responsible person

Hamid Reza Kouhpayeh

Street address

Bu Ali hospital, Shariati St

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9813617697

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hkouhpayeh@yahoo.com

2

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Mandana Pouladzadeh

Street address

Razi hospital,In front of the governorate, Palestine Street, Amaniyeh,

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Ahwaz

Province

Khouzestan

Postal code

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Phone

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Email

Mandanapouladzadeh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

High Educational and Research Institute of Transfusion Medicine

Full name of responsible person

Mahtab Maghsoodlu

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High Educational and Research Institute of Blood Transfusion Medicine, Shahid Hemmat HWY at Sheikh Fazlollah Nouri HWY, next to Milad Tower

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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

High Educational and Research Institute of Transfusion Medicine

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

Iran Blood Transfusion Organization

Full name of responsible person

Saeed Mohammadi

Position

Technical Deputy and New Technologies

Latest degree

Ph.D.

Other areas of specialty/work

Hematology

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran Blood Transfusion Organization
Full name of responsible person
Peyman Eshghi
Position
Chief executive officer of the Blood Transfusion Organization of Iran
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
Shamsi Okati
Position
Specialist physician
Latest degree
Specialist
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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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Information about the main and secondary consequences can be shared.
When the data will become available and for how long
The access period will start 6 months after the results are printed.
To whom data/document is available
Researchers working at academic and scientific institutes, as well as craftsmen, can apply to receive them.
Under which criteria data/document could be used
The data/document can be used if the reasons of the request are determined . The type of analysis that will be performed on the delivered data are specified. Any type of data exploitation must be approved by the project supervisor.
From where data/document is obtainable
He or she can refere to the High Educational and Research Institute of Blood Transfusion Medicine. Shahid Hemmat HWY at Sheikh Fazlollah Nouri HWY, next to Milad Tower Phone:0098 21 88601564 Website: ibto.ir
What processes are involved for a request to access data/document
The High Educational and Research Institute of Blood Transfusion Medicine will receive and review the request, coordinate with the project manager, provide data files and inform to the applicant.
Comments