

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Oct 2020

The Effect of Convalescent Plasma Therapy on the Outcomes of Patients with 19-COVID

Protocol summary

Registration timing: **prospective**

Study aim

Evaluation of convalescent plasma therapy in the treatment of patients with COVID-19 disease

Last update: **2020-05-09, 1399/02/20**

Update count: **0**

Design

In this intervention study, 60 patients who have the criteria to enter the study are divided into two groups of 30 people by block randomization method. Patients are explained about treatment methods and their benefits and complications, and informed consent is obtained.

Registration date

2020-05-09, 1399/02/20

Registrant information

Name

Somaieh Matin

Name of organization / entity

Ardabil University of Medicine Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3373 3011

Email address

s.matin@arums.ac.ir

Settings and conduct

1. Convalescent plasma will be received from those recovering from COVID-19 disease previously hospitalized at Emam Khomeini, Emam Reza and Sabalan Hospitals 2- Convalescent Plasma received from volunteers will be infused to the patients with confirmed infection of COVID-19.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Blood oxygenation saturation <90% 2. Abnormal lung CT scan 3. Significant shortness of breath 4. Fever 5. Not improving in the next 48 hours 6. There is no possibility of discharge of patient in the next 48 hours 7. Patient consent Exclusion criteria 1. The patient should not be connected to a ventilator . 2. The patient has not given consent.

Expected recruitment start date

2020-05-12, 1399/02/23

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Intervention group: The recipient plasma group will receive 500 ml in 4 hours. Control group: The control group receives only routine treatment.

Main outcome variables

Reduction in all causes mortality; reduction of hospital stay

Scientific title

The Effect of Convalescent Plasma Therapy on the Outcomes of Patients with 19-COVID

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150808023559N21**

Registration date: **2020-05-09, 1399/02/20**

Public title

The Effect of Convalescent Plasma Therapy on Patients with 19-COVID

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of Covid19 based on PCR Blood oxygen saturation less than 90% No recovery within 48 hours of routine treatment

Exclusion criteria:

History of allergic reactions to blood products injection

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are assigned randomly by blocking in one of the two specified groups and after selecting the envelope for each patient, before starting the treatment regimen envelope will be opened and based on the protocol, one of two methods will be selected.

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 Ardabil University of Medical Sciences

Street address

Daneshghah street, Ardabil University of Medical Sciences

City

Ardabil

Province

Ardabil

Postal code

53141-56198

Approval date

2020-04-05, 1399/01/17

Ethics committee reference number

IR.ARUMS.REC.1399.052

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

Reduction in all causes mortality

Timepoint

At the time of discharge of patients

Method of measurement

Patient documents

Secondary outcomes

1

Description

Reduction of hospital stay

Timepoint

At the time of discharge of patients

Method of measurement

Patient documents

Intervention groups

1

Description

Intervention group: Patients in the intervention group, in addition to routine treatment, will receive convalescent Plasma extracted from improved patients from 19-COVID in the amount of 500 ml over a period of 4 hours.

Category

Treatment - Drugs

2

Description

Control group: They only receive routine treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini and Sabalan Hospital of Ardabil

Full name of responsible person

Effat Irani Jam

Street address

Azadi Street

City

Ardabil

Province

Ardabil

Postal code

561577663

Phone

+98 45 3325 1402

Email

dr.jam733@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

Shahab Bohlooli

Street address

Iran, Ardabil, Daneshghah Street, Ardabil University of Medical Sciences

City

Ardabil

Province

Ardabil

Postal code

543421329

Phone

+98 45 3325 1410

Email

research@arums.ac.ir

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

Yes

Title of funding source

Ardabil 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**

Ardabil University of Medical Sciences

Full name of responsible person

Effat Irani Jam

Position

assistant of professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Iran, Ardabil, University Street, Ardabil University of Medical Sciences

City

Ardabil

Province

Ardabil

Postal code

5615677489

Phone

+98 45 3325 1410

Email

dr.jam733@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

Somaieh Matin

Position

Assistant of Professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Iran, Ardabil, University Street, Ardabil University of Medical Sciences

City

Ardabil

Province

Ardabil

Postal code

5615783143

Phone

+98 45 3325 1410

Email

s.matin@arums.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

Somaieh Matin

Position

استادیار

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Emam Khomeini Hospital, Ardabi University of Medical

Sciences, Ardabil, Iran

City

Ardabil

Province

Ardabil

Postal code

5615783143

Phone

+98 45 3371 8915

Email

s.matin@arums.ac.ir

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

Not applicable

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

Not applicable

Data Dictionary

Not applicable