Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

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

Protocol summary

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

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20150808023559N21**
Registration date: **2020-05-09, 1399/02/20**
Registration timing: **prospective**

Last update: **2020-05-09, 1399/02/20**
Update count: **0**
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

Recruitment status
Recruitment complete
Funding source

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

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

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