Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of the effects of COVID-19 convalescent plasma in acute respiratory distress syndrome due to COVID-19

Protocol summary

Study aim
Determination of the effects of COVID-19 convalescent plasma in acute respiratory distress syndrome due to COVID-19

Design
Present study is randomized, parallel, clinical trial.

Settings and conduct
the present study will be done in hospitalized COVID-19 patients at Urmia University of Medical Sciences hospitals. patients divided into 3 groups that will receive standard treatment and 2 of them will receive different doses of convalescent plasma.

Participants/Inclusion and exclusion criteria
1-Positive PCR test 2-dyspnea 3-respiratory frequency ≥ 30/min 4-blood oxygen saturation ≤ 93% 5-the partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300 6-lung infiltrates > 50% within 24 to 48 hours 7- The life-threatening disease is defined as respiratory failure

Intervention groups
1-control group: standard treatment 2-first interventional group: 2-5 cc/kg convalescent plasma (days 1,3,5) 3-second interventional group: 8-10 cc/kg convalescent plasma (day 1)

Main outcome variables
hospitalization time, ICU admission time, mechanical ventilation time, survival rate.

General information

Reason for update

Acronym
COVID-19

IRCT registration information
IRCT registration number: **IRCT20200501047258N1**
Registration date: **2020-05-04, 1399/02/15**
Registration timing: **registered_while_recruiting**
Last update: **2020-05-04, 1399/02/15**
Update count: **0**

Registration date
2020-05-04, 1399/02/15

Registrant information

Name
Rahim Asghari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 44 3345 7286

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asghari.r@umsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-04, 1399/02/15

Expected recruitment end date
2021-05-05, 1400/02/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation of the effects of COVID-19 convalescent plasma in acute respiratory distress syndrome due to COVID-19

Public title
effects of convalescent plasma in COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Positive PCR test The life-threatening disease is defined as respiratory failure dyspnea respiratory frequency ≥ 30/min blood oxygen saturation ≤ 93% partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300 lung infiltrates > 50% within 24 to 48 hours

Exclusion criteria:

Pregnancy Hypersensitivity to blood or blood products Uncontrolled bacterial infection Disagreement

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

More than 1 sample in each individual

Number of samples in each individual: **5**

CD4, CD8 Lymphocytes/ IL-6, TNF/ Plt/ Hb/ WBC/ Lymphocytes/ Neutrophils/ BUN/ Cr/ AST/ ALT/ ALP/ Bill (T,D)/ Vitamin D/ D-dimer

Randomization (investigator's opinion)

Randomized

Randomization description

We use block randomization and according to the study design patients will be divided into two groups (severe and critical). firstly, we will create two separate blocks size equal to 6 (AABBCC). Secondly, we will list all permutation of them and assigned code for each permutation. We will select 10 blocks using a simple random method for two study groups (severe and critical).

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

Urmia University of Medical Sciences

Street address

Resalat Street, UMSU.

City

Urmia

Province

West Azarbaijan

Postal code

57147-83734

Approval date

2020-04-26, 1399/02/07

Ethics committee reference number

IR.UMSU.REC.1399.030

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

Hospitalization time

Timepoint

0, 1, 3, 7, 14 days

Method of measurement

check list

2

Description

ICU admission time

Timepoint

0, 1, 3, 7, 14 days

Method of measurement

check list

3

Description

mechanical ventilation time

Timepoint

0, 1, 3, 7, 14 days

Method of measurement

check list

4

Description

survival rate

Timepoint

0, 1, 3, 7, 14 days

Method of measurement

check list

Secondary outcomes

1

Description

CT scan

Timepoint

0- 1- 3- 7- 14 days

Method of measurement
CT scan

2

Description
serological tests
Timepoint
0- 1- 3- 7- 14 days
Method of measurement
ELISA

3

Description
hematological markers
Timepoint
0- 1- 3- 7- 14 days
Method of measurement
flowcytometry

4

Description
clinical findings
Timepoint
0- 1- 3- 7- 14 days
Method of measurement
check list

Intervention groups

1

Description
Intervention group 1: hospitalized patients received convalescent plasma with 2-5 cc/kg transfused on 1, 3, 5 days after treatment that treated with the standard national guideline.
Category
Treatment - Drugs

2

Description
Intervention group 2: hospitalized patients received convalescent plasma with 8-10 cc/kg transfused on 1 day after treatment that treated with the standard national guideline.
Category
Treatment - Drugs

3

Description
Control group: hospitalized patients treated with the standard national guideline.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
hospitals of UMSU
Full name of responsible person
Rahim Asgari
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Resalat street, UMSU
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Iraj Mohebbi
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Urmia University of Medical University
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
Oroumia University of Medical Sciences
Full name of responsible person
Rahim Asghari
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Hematology & medical oncology
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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
Not applicable
Title and more details about the data/document
Aggregate data can be shared.
When the data will become available and for how long
A year after beginning of study.
To whom data/document is available
this study only available for people working in academic institutions.
Under which criteria data/document could be used
take permission from UMSU and research team members.
From where data/document is obtainable
Resalat st, UMSU
What processes are involved for a request to access data/document
Contact with UMSU
Comments