

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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 $\geq$ 30/min 4-blood oxygen saturation $\leq$ 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)

Phone

+98 44 3345 7286

Email address

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 $\geq$ 30/min blood oxygen saturation $\leq$ 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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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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Latest degree

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Latest degree

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Other areas of specialty/work

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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