Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect ofPlasmapheresis on hypoxia in patients suffering from COVID-19: A randomized clinical trial

Protocol summary

Study aim
Determination of the effect of plasmapheresis on hypoxia and inflammatory factors in patients with new coronavirus (Covid-19).

Design
Clinical trial with control group, with parallel groups,open-label, randomized, phase 3 on 40 patients. Simple randomization method was used as coding method.(Odd and even)

Settings and conduct
Patients referred to Hazrat Vali-e-Asr Hospital in Birjand with Covid-19 infection whose disease has been confirmed by real-time PCR molecular test or on the basis of lung CT scan symptoms and their infection is severe or threatening Life is randomly assigned to the case and control groups and the study was conducted as an open label. In the intervention group, in addition to the standard treatment of Covid-19, plasmapheresis was also performed for the patients.

Participants/Inclusion and exclusion criteria
Definitive diagnosis of Covid-19 based on taking a sample from the pharynx and laboratory PCR confirmation, lung involvement of more than 50% and SPO2 levels below 80% without oxygen or below 88% with oxygen or IL above 10 or ferritin above 1500, patients who have not responded to other Covid-19 treatments, age over 18 and consent to participate in the study;Exclusion criteria include a history of albumin sensitivity, a history of heparin allergy who cannot receive heparin as an anticoagulant during plasmapheresis, patients with hypocalcemia.

Intervention groups
Patients in the intervention group, in addition to the standard treatment of Covid-19, will undergo the intervention (plasmapheresis). For each patient, if the clinical symptoms do not improve, plasmapheresis will be performed up to 3 times.In this group, patients received the standard treatment of Covid-19 according to the national protocol.

Main outcome variables
Percentage of blood oxygen saturation, Arterial blood oxygen pressure in the analysis of blood gases

General information

Reason for update

Acronym
BPS

IRCT registration information
IRCT registration number: **IRCT20220517054899N1**
Registration date: **2022-08-13, 1401/05/22**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-13, 1401/05/22**
Update count: **0**

Registration date
2022-08-13, 1401/05/22

Registrant information

Name
Vajihollah Raeesi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 56 3239 5000

Email address
vajehraeesi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-22, 1401/04/31

Expected recruitment end date
2023-03-22, 1402/01/02

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect ofPlasmapheresis on hypoxia in patients suffering from COVID-19: A randomized clinical trial

Public title
The effect of Plasmapheresis on hypoxia in patients suffering from COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of Covid-19 based on taking a sample from the pharynx and PCR laboratory confirmation Lung involvement more than 50% SPO2 levels below 80% without oxygen or below 88% with oxygen or IL above 10 or ferritin above 1500 Patients who have not responded to other Covid-19 treatments Age over 18 years and consent to participate in the study
Exclusion criteria:
History of albumin sensitivity Heparin allergy who cannot receive heparin as an anticoagulant during plasmapheresis Patients with hypocalcemia (citrate used in the plasmapheresis process exacerbates hypocalcemia)
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization based on the table of random numbers. A set of numbers without a specific pattern and order and in a completely random manner are in the form of a table. The direction of reading the numbers in this table will be from top to bottom and right to left. Even numbers will be considered for the intervention group and odd numbers for the control group.
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 Birjand University of Medical Sciences
Street address
No. 28, Ghafari Ave., zakariyay razi Blvd وbirjand University of Medical Sciences
City
birjand
Province
South Khorasan
Postal code
9717964151
Approval date
2022-04-27, 1401/02/07
Ethics committee reference number
IR.BUMS.REC.1401.059

Health conditions studied

1

Description of health condition studied
Corona virus (Covid-19)
ICD-10 code
Pneumonia
ICD-10 code description
J12.81

Primary outcomes

1

Description
Percentage of blood oxygen saturation (SPO2)
Timepoint
On days zero (before the intervention), days one, three, five and seven after the intervention
Method of measurement
Pulse oximeter Bitmos Gmbh made in Germany

2

Description
Arterial blood oxygen pressure in the analysis of blood gases Pao2
Timepoint
On days zero (before the intervention), days one, three, five and seven after the intervention
Method of measurement
Blood sample to measure blood gases

Secondary outcomes

1

Description

Duration of hospitalization of the patient

Timepoint

End of hospitalization or death of the patient

Method of measurement

By day

2

Description

C-reactive protein (CRP) Factor

Timepoint

On days zero (before the intervention), days one, three, five and seven after the intervention

Method of measurement

Blood Test Prestige 24i machine made in Japan

Intervention groups

1

Description

Intervention group: Patients in the intervention group, in addition to the standard treatment of Covid-19, (dexamethasone at a dose of 6 mg per day and remedSivir at a dose of 200 mg on the first day and then 100 mg daily for 7 days) will undergo the intervention (plasmapheresis). Each time plasmapheresis is performed, 40 ml per kg of body weight of the patient's plasma is replaced with 5% human albumin and 0.9% normal saline, and for each patient, if the clinical symptoms do not improve, plasmapheresis will be performed up to 3 times.

Category

Treatment - Drugs

2

Description

Control group: In this group, patients received the standard treatment of Covid-19 according to the national protocol (Hedhexamethasone 6 mg daily and Ramdesiver 200 mg on the first day and 100 mg daily for 7 days).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Vajehallah Raeesi

Street address

No. 28. ghafari Ave., zakariyay razi blvd. birjand university of medical sciences

City

Birjand

Province

South Khorasan

Postal code

9717964151

Phone

+98 56 3244 2055

Email

vajehehraeesi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Vajehallah Raeesi

Street address

No.28, ghafari Ave., Zakariyay Razi Blvd.Birjand university of medical sciences

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Vajehraeesi@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Vajehallah Raeesi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

No. 28, West, Ghafari Ave., Zakariyay Razi

Blvd.Birjand university of medical sciences

City
Birjand

Province
South Khorasan

Postal code
9717964151

Phone
+98 56 3162 2430

Email
vajehraeesi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Birjand University of Medical Sciences

Full name of responsible person
Vajehallah Raeesi

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Urology

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Phone
+98 56 3162 2430

Email
vajehraeesi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Birjand University of Medical Sciences

Full name of responsible person
Vajehallah Raeesi

Position
Assistant Professor

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Other areas of specialty/work
Urology

Street address
No. 28, Ghafari Ave.,Zakariyay Razi Blvd. birjand university of medical sciences

City
Birjanad

Province
South Khorasan

Postal code
9717964151

Phone
+98 56 3162 2430

Email
vajehraeesi@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available

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
Undecided - It is not yet known if there will be 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
-

When the data will become available and for how long
-

To whom data/document is available
-

Under which criteria data/document could be used
-

From where data/document is obtainable
-

What processes are involved for a request to access data/document
-

Comments
-