Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of albumin administration on attenuation, lung involvement and blood oxygenation of patients with Covid-19 admitted to intensive care unit with albumin level less than 3 and 2 g dl (Clinical Trial)

Protocol summary

Study aim

Determining the effectiveness of albumin administration on attenuation, lung involvement and blood oxygen in patients with covid-19 hospitalized in the intensive care unit with an albumin level less than 3 grams per deciliter

Design

A non-randomized double-blind clinical trial with intervention and control groups, sample size of 52 patients, trial phase 2-3, and allocation of study groups will be conducted in parallel.

Settings and conduct

52 participants with entry conditions, among the patients with covid-19 hospitalized in the special care department referring to Shahid Madani Hospital Karaj in 2022, are divided into two control and intervention groups. For the study subjects, before the random assignment, it is explained how the work process is and they may receive one of the two treatments randomly, so the patient and Outcome assessor will not know which group she is in.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 years and above; PCR test positive; Observation of lung involvement in CT scan; Hypoxia (arterial oxygen saturation less than 90%) Exclusion criteria: Hypoxia (arterial oxygen saturation more than 90%)

Intervention groups

Intervention group: After albumin reaches a level of less than 3 grams per deciliter, albumin will be administered in the amount of three vials daily and every eight hours for seven days. Control group: If the albumin drops to less than 2 grams per deciliter, the same treatment as the intervention group will be performed.

Main outcome variables

Mortality rate; lung involvement rate; blood oxygen saturation percentage.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221011056144N1**
Registration date: **2022-12-14, 1401/09/23**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-14, 1401/09/23**
Update count: **0**

Registration date

2022-12-14, 1401/09/23

Registrant information

Name

Afsaneh Zandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3428 7383

Email address

afsanehzandi24@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-10, 1401/09/19

Expected recruitment end date

2023-02-18, 1401/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of albumin administration on attenuation, lung involvement and blood oxygenation of patients with Covid-19 admitted to intensive care unit with albumin level less than 3 and 2 g dl (Clinical Trial)

Public title
The effect of albumin administration on mortality rate, lung involvement rate and blood oxygen in patients with covid-19 hospitalized in the intensive care unit

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 years and above PCR test positive Observation of lung involvement in CT scan Hypoxia (arterial oxygen saturation less than 90%) Patients with consent to participate in the study

Exclusion criteria:
Hypoxia (arterial oxygen saturation more than 90%)

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
For the study subjects, before the random assignment, it is explained how the work process is and they may receive one of the two treatments randomly, and the drug used for the subjects is not known in advance, the form of the intervention drug and placebo and also, the frequency and times of administration of these two will be similar so that it is not possible for the patient and Outcome assessor to distinguish them from each other, so the patient and Outcome assessor will not know which group she is in.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Alborz University of Medical Sciences

Street address
Second floor, Deputy of Research and Technology, Saffarian Alley, 45 meters from Golshahr, Karaj.

City
Karaj

Province
Alborz

Postal code
3149779453

Approval date
2022-11-11, 1401/08/20

Ethics committee reference number
IR.ABZUMS.REC.1401.215

Health conditions studied

1

Description of health condition studied
Patients with covid-19

ICD-10 code
U07.1

ICD-10 code description
Covid-19, Virus identified

Primary outcomes

1

Description
Mortality rate

Timepoint
Seven days after treatment

Method of measurement
Based on the patient's file

2

Description
Lung involvement rate

Timepoint
Seven days after treatment

Method of measurement
CT scan findings

3

Description
Blood oxygen saturation percentage

Timepoint
Seven days after treatment

Method of measurement
Non-invasive monitoring device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After albumin reaches a level of less than 3 grams per deciliter, 20% albumin in 50 ml vials (company: CSL BEHRING, country of manufacture: Germany) will be administered, three vials daily, every eight hours for seven days.
Category
Treatment - Drugs

2

Description
Control group: If the albumin drops to less than 2 grams per deciliter, the same treatment as the intervention group will be performed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Madani Hospital
Full name of responsible person
Reza Alizadeh Kashani MD
Street address
Jahanshahr Street
City
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Province
Alborz
Postal code
3143744693
Phone
+98 26 3442 7001
Email
Dralizadeh.reza@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Hatam Godini P.H.D
Street address
Saffarian alley, 45 meters from Golshahr, Karaj
City
Karaj
Province
Alborz
Postal code
3198764653
Phone
+98 26 3464 3705
Email
h.godini@abzums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Karaj 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
Karaj University of Medical Sciences
Full name of responsible person
Afsaneh Zandi MD
Position
Anesthesiology resident
Latest degree
Specialist
Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is 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
The whole data can be shared after unidentifiable people.
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Only available to scholars working in academic and academic institutions.
Under which criteria data/document could be used
Employed in research centers
From where data/document is obtainable
Person responsible for scientific inquiries
What processes are involved for a request to access data/document
Send email to person responsible for scientific inquiries (afsanehzandi24@gmail.com).
Comments