

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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

Karaj

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

Anesthesiology

Street address

Jahanshahr Street

City

Karaj

Province

Alborz

Postal code

3143744693

Phone

0098 26 344420

Email

afsanehzandi24@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Afsaneh Zandi MD

Position

Anesthesiology resident

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Person responsible for updating data**Contact****Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Afsaneh Zandi MD

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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