

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effects of alpha-1-antitrypsin on the progression of covid-19 disease: a randomized control trial

Protocol summary

Study aim

In this research, we aim to present the potential role of AAT as an anti-viral and anti-inflammatory agent in SARS-CoV-2 infection.

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 50 patients. It is used for randomization with blocking based on alpha-1-antitrypsin serum level and random numbers.

Settings and conduct

Coronary patients admitted to the ICU of hospitals affiliated to Shahid Beheshti University of Medical Sciences will be evaluated. The present study will be a double-blind randomized controlled clinical trial with parallel groups. The research population is 50 patients. The duration of the study is four weeks and the intervention is weekly. The dose used is 60mg/kgBW and it is an injectable drug. The patient, researcher and health care provider will be blinded. For this purpose, a placebo with the appearance of the drug is used.

Participants/Inclusion and exclusion criteria

People who are willing to participate in the research, over 18 years of age, with a positive PCR test for corona or lung involvement in imaging, with oxygen saturation less than 93% in room air, or RR>40 with or without fever. Patients suffering from underlying diseases are not included in the study. People who use anti-coagulant drugs, hormonal drugs, and other illegal drugs, or who consume alcohol, are pregnant or lactating, are not included in the study.

Intervention groups

The intervention group received alpha-1-antitrypsin and the control group received placebo (normal saline 0.9%).

Main outcome variables

The level of serum alpha-1 antitrypsin, the number of neutrophils and lymphocytes, Mortality rate and hospitalization time, the ratio of neutrophils to lymphocytes, and the serum protein levels of CRP, ESR, interleukin 6, IgA, and anti-IgA antibody.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110510006431N6**

Registration date: **2022-10-29, 1401/08/07**

Registration timing: **prospective**

Last update: **2022-10-29, 1401/08/07**

Update count: **0**

Registration date

2022-10-29, 1401/08/07

Registrant information

Name

Mahdi Shadnough

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

shadnough@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of alpha-1-antitrypsin on the progression of covid-19 disease: a randomized control trial	
Public title	The effect of alpha-1-antitrypsin on the progression of covid-19 disease
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Age above 18 years The presence of shortness of breath Positive PCR test for corona or lung involvement in imaging Signing informed consent and readiness to participate in the plan Exclusion criteria: Patients suffering from underlying diseases including pulmonary hypertension, kidney failure, seizures, depression, chronic hepatitis, cirrhosis and cholestatic liver diseases and pulmonary embolism (in the past 3 months) Use of anti-coagulant drugs such as warfarin, hormonal drugs and other illegal drugs (within the past 30 days) Alcohol consumption Pregnancy or breastfeeding Allergy to AAT drug Having IgA deficiency No smoking in the last 6 months
Age	From 18 years old
Gender	Both
Phase	3
Groups that have been masked	- Participant - Care provider - Investigator
Sample size	Target sample size: 50
Randomization (investigator's opinion)	Randomized
Randomization description	The participants were divided into two groups based on the level of AAT serum by Stratified Blocked Randomization. a random sequence will generate. For this purpose, we will use random sequence generation software. We will calculate random sequences in the range of 1-2 using the stat trek software (https://stattrek.com/statistics/random-number-generator.aspx) for two groups one and two (for example: 2 1 1 2 1 2 1 1 2 2 1 1 2 1 2 2 2 1 1 2 1 2 1). The numbers 1 are assigned to the intervention group 1 (alpha-1-antitrypsin) and the numbers 2 are assigned to the control group. Each number will represent a group according to the defined numbers. With this method, at the end, we will have a specific sequence of codes 1 and 2, which shows the blocks who are going to be included in the study, in which group they should be placed. We wrote the codes on a piece of paper and put them in an envelope to use during sampling. In this way, after checking the entry criteria and if the client wishes, we will enter each block entered into the study into the groups according to our predetermined list.
Blinding (investigator's opinion)	Double blinded
Blinding description	In order to blind the patient, the researcher and the clinical caregiver, the alpha-1-antitrypsin and placebo will be used that have the same appearance, but the patient, the researcher and the health care provider will not be informed that each person is using the alpha-1-antitrypsin or the placebo.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	1 Ethics committee Name of ethics committee Research Ethics Committees of Vice-Chancellor in Research Affairs - Shahid Beheshti University of Me Street address Yemen St. - Shahid Arabi St City Tehran Province Tehran Postal code 1985717443 Approval date 2022-10-02, 1401/07/10 Ethics committee reference number IR.SBMU.RETECH.REC.1401.473
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 the ratio of neutrophils to lymphocytes Timepoint At the first and at the 4th week of the study Method of measurement immunoassay

2

Description

ESR

Timepoint

At the first and at the 4th week of the study

Method of measurement

Westergren method and ESR tube

3

Description

CRP

Timepoint

At the first and at the 4th week of the study

Method of measurement

Spectrophotometry

4

Description

IL-6

Timepoint

At the first and at the 4th week of the study

Method of measurement

immunoassay

5

Description

Mortality rate

Timepoint

the 4th week of the study

Method of measurement

observation

6

Description

hospitalization time

Timepoint

the 4th week of the study

Method of measurement

observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receiving alpha 1 antitrypsin drug. Type a 1-glycoprotein is a relatively small and polar molecule that acts as an extracellular inhibitor of serine proteases. This enzyme is one of the first defense proteins of the body. The dosage is 60 mg/kgBW as an injection once a week. for four weeks.

Category

Treatment - Drugs

2

Description

Control group: normal saline 0.9% with the same dose and repetition and time as the interfering substance

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospitals covered by Shahid Beheshti University of Medical Sciences, Tehran

Full name of responsible person

Mahdi Shadnoush

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

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1985717413

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Beheshti Faculty of Pharmacy, Protein Technology Research Center, Vali Asr Street, Niayesh Highway Intersection, Tehran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahdi shadnough

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Full name of responsible person

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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