Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Investigating the Effect of National Protocol for Treatment of Covid-19 Disease on Amino Acids, Carnitines and Acylcarnitine's Profile of Plasma in Hospitalized Patients

Protocol summary

Study aim

Determining the plasma concentrations of amino acids, carnitines and acylcarnitine's in hospitalized patients with covid-19 using Liquid Chromatography, Mass Spectrometry (LC-MSS) method and investigating the relationship of these metabolic factors with side effects in this patients

Design

A prospective, single, unblinded, phase 2-3 clinical trial on 30 patients

Settings and conduct

Place of study: Masih Daneshvari Hospital, How to conduct the study: Blood samples are placed into a liquid chromatography-mass spectrometry system after preparation. By testing the significance of the difference in the average concentrations of amino acids, carnitines and acylcarnitine's of the intervention group and the standard mean concentrations , the effect of the disease on the concentrations of these metabolic factors will be examined

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with a positive PCR test; moderate to severe pulmonary involvement; respiratory rate less than or equal to 30 per minute and the percentage of oxygen saturation less than or equal to 94 Non-inclusion criteria: Patients with mechanical ventilation and psychotic disorders

Intervention groups

From 30 patients, blood samples is collected on Guthrie Whatman 903 paper on the third day of hospitalization

Main outcome variables

Plasma levels of amino acids, carnitines and acylcarnitine's, side effects and clinical outcomes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151227025726N35**
Registration date: **2023-10-18, 1402/07/26**
Registration timing: **prospective**

Last update: **2023-10-18, 1402/07/26**
Update count: **0**

Registration date

2023-10-18, 1402/07/26

Registrant information

Name

Farzaneh Dastan

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 270 5933

Email address

f_dastan@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-15, 1402/08/24

Expected recruitment end date

2024-11-14, 1403/08/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of National Protocol for Treatment of Covid-19 Disease on Amino Acids, Carnitines and Acylcarnitine's Profile of Plasma in Hospitalized Patients

Public title
Effect of Coronavirus Treatment Protocol on Metabolic Factors of Plasma
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with positive PCR test Patients with moderate to severe pulmonary involvement Patients with respiratory rate less than or equal to 30 breaths per minute Patients with percentage of saturated oxygen less than or equal to 94
Exclusion criteria:
Patients with mechanical ventilation Patients with psychotic disorders
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committe of Shahid Beheshti University of Medical Sciences
Street address
3 rd floor, School of Medicine, Evin Street, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1983963113
Approval date
2022-03-14, 1400/12/23
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1401.022

Health conditions studied

1

Description of health condition studied
COVID-19 pneumonia
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Plasma concentrations of amino acids, carnitines and acylcarnitine's
Timepoint
On the third day of hospitalization
Method of measurement
Liquid chromatography-Mass spectrometry

Secondary outcomes

1

Description
Adverse drug reaction
Timepoint
At the end of the study
Method of measurement
Medical record

Intervention groups

1

Description
Intervention group: From 30 patients receiving the national protocol for treatment of Covid-19 disease, blood samples is taken on Guthrie Whatman 903 paper on the third day of hospitalization
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Farzaneh Dastan

Street address
Masih Daneshvari Hospital, Shahid Bahonar Street (Niyavaran), Darabad, Tehran
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Farzad Kobarfard
Street address
Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences, Intersection of Niayesh Highway, Valieasr St.
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1991953381
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Email
kobarfard@sbmu.ac.ir
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
Farzaneh Dastan
Position
Assisstant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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Name of organization / entity
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Professor
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Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sadaf Ehdaeivand
Position
Pharmacy student
Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy
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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
All potential data can be shared after blinding
When the data will become available and for how long
Six months after publishing the results
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
For research purposes and meta-analysis studies
From where data/document is obtainable
Dr. Farzaneh Dastan, Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran
What processes are involved for a request to access data/document
Official letter to the researchers through Email (fzh.dastan@gmail.com)
Comments