Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of atorvastatin on on inflammatory factors and prognosis outcomes in patients with Covid 19, hospitalized in Hajar Hospital, Shahrekord University of Medical Sciences, 2021

Protocol summary

Study aim
Determination of the effect of atorvastatin on inflammatory and cirrhotic factors in patients with Covid 19 infection, hospitalized in Hajar Hospital, Shahrekord University of Medical Sciences

Design
This double-blind clinical trial study will be performed on 80 patients with Covid 19 confirmed by molecular test, hospitalized in Hajar Hospital. Patients are randomly divided into two groups of 40 control and the group receiving atorvastatin. Elevated liver enzymes, disease prognosis, and sequelae of Covid virus 19 follow-up for clinical signs of fever, chills, shortness of breath, breathing (bipap or intubation), and severity of disease on days 1, 7, and 14. Duration of hospitalization, mortality rate are also checked.

Settings and conduct
Patients admitted to Hajar Educational and Medical Center in Shahrekord in 2021

Participants/Inclusion and exclusion criteria
Patients with Covid 19 with approved molecular test admitted to Hajar Hospital in Shahrekord,2021

Intervention groups
Group 1: Patients treated with standard diet + atorvastatin 40 mg (20) daily for 14 days Group 2: Patients are treated with standard diet + placebo.

Main outcome variables
Elevated liver enzymes, disease prognosis, and sequelae of Covid virus 19 follow-up for clinical signs of fever, chills, shortness of breath, breathing (bipap or intubation), and severity of disease on days 1, 7, and 14. Duration of hospitalization, mortality rate are also checked.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210426051090N1**
Registration date: **2021-06-12, 1400/03/22**
Registration timing: **prospective**

Last update: **2021-06-12, 1400/03/22**
Update count: **0**

Registration date
2021-06-12, 1400/03/22

Registrant information

Name
Shahab Moghaddam

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 38 3222 0016

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st-moghaddam.sh@skums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01

Expected recruitment end date
2021-08-23, 1400/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of atorvastatin on on inflammatory factors and

prognosis outcomes in patients with Covid 19, hospitalized in Hajar Hospital, Shahrekord University of Medical Sciences, 2021

Public title
The effect of atorvastatin on Covid 19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with confirmed molecular test of blood oxygen saturation level SpO2 less than 90% in room air Patients with pulmonary involvement in radiological studies Do not take statins The patient is not in a state of shock and sepsis
Exclusion criteria:
Having advanced heart disease (CHF) Liver disease (based on primary LFT) Incidence of statin side effects Long-term use of corticosteroids to die Pulmonary underlying disease
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization of patients will be done by the responsible researcher using Excel software. Randomization will be done by creating blocks. Blocks will be considered in variable sizes including 4 or 6 or 8 patients. In order to randomly assign patients in the two groups receiving medication and placebo, a specific code including 2 letters and a number will be assigned to each patient. This code will be unique to each patient (for example, code AB1 for patient number one). Only the researcher in charge of the study will know that each code is assigned to the drug or placebo group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The drugs required for the participants in the study will be fully covered at the research site will be available to the participants in the study. Study participants and evaluators of the final outcome of patients will not be aware of the drug or placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahre-kord University of Medical Sciences
Street address
Parastar Aven
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8816754633
Approval date
2021-05-12, 1400/02/22
Ethics committee reference number
IR.SKUMS.REC.1400.046

Health conditions studied

1

Description of health condition studied
Covid-19
ICD-10 code
B34.2
ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
O2 Saturation
Timepoint
1 and 7 days after the start of the study
Method of measurement
Pulse oximetry device

2

Description
FBS
Timepoint
1 and 7 days after the start of the study
Method of measurement
blood test

3

Description
IL-6
Timepoint
1 and 14 days after the start of the study
Method of measurement

blood test

4

Description
Alt، Ast ،Alkp ، Bill total ، Bill direct
Timepoint
1 and 7 and 14 days after the start of the study
Method of measurement
blood test

5

Description
BUN, Na, K, Cr
Timepoint
1 and 7 days after the start of the study
Method of measurement
blood test

6

Description
PT, PTT, INR
Timepoint
1 and 7 days after the start of the study
Method of measurement
blood test

7

Description
TG, Total Cholesterol, LDL, HDL
Timepoint
1 and 7 days after the start of the study
Method of measurement
blood test

8

Description
CBC(diff)
Timepoint
1 and 7 days after the start of the study
Method of measurement
blood test

9

Description
LDH
Timepoint
1 and 7 and 14 days after the start of the study
Method of measurement
blood test

10

Description
ESR
Timepoint
1 and 7 and 14 days after the start of the study
Method of measurement
blood test

11

Description
CRP
Timepoint
1 and 7 and 14 days after the start of the study
Method of measurement
blood test

12

Description
Ferritin
Timepoint
1 and 7 and 14 days after the start of the study
Method of measurement
blood test

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Patients receiving standard diet treatment (according to national protocol) + placebo.
Category
Treatment - Drugs

2

Description
Intervention group: Patients with standard diet treatment + atorvastatin 40 mg made by Mehr Daroo Pharmaceutical Company daily for 14 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hajar Hospital, Shahrekord
Full name of responsible person
Ahmad Raesi
Street address
Parastar Aven
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Mehraban Sadeghy
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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
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Shahab Moghaddam
Position
Resident
Latest degree
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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

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only part of the data such as information about the main outcome or the like can be shared.

When the data will become available and for how long

2021-2022

To whom data/document is available

En The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

I have not decided yet

From where data/document is obtainable

I have not decided yet

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

I have not decided yet

Comments