

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)

Phone

+98 38 3222 0016

Email address

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

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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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City

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Chahar-Mahal-va-Bakhtiari

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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

Medical doctor

Other areas of specialty/work

Internal Medicine

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Latest degree

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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

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