

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Atorvastatin effect in Clinical and Laboratory findings of patients with COVID-19 admitted RAZI referral hospital in Mazandaran State: A Randomized Clinical Trial

Protocol summary

Study aim

The purpose of this study is to investigate the effect of Atorvastatin in the clinical and laboratory outcomes of patients with Coronavirus Disease 2019 (COVID-19) hospitalized in RAZI referral center in Mazandaran State

Design

Two arm parallel group randomized trial with blinded postoperative care and outcome assessment. Two group of 50 patients with confirmed COVID-19 will be entered to the study. Patients will be admitted to the study in order of hospitalization and will be assigned one in between to each group.

Settings and conduct

Patients in intervention group will be under treatment with Oral Atorvastatin 40 mg for 5 days in addition to standard care. C-reactive Protein level will be measured at the beginning and after 5 days. Patient's treatment process will be recorded and outcomes will be assessed.

Participants/Inclusion and exclusion criteria

Patients with Confirmed COVID-19, aged 20-50 years without prior history of cardiovascular disease, Statin use and under treatment with Chloroquine will be entered to the study; patients using Kaletra; prior liver damage; prior myositis will be excluded because of adverse reaction with statins.

Intervention groups

Both groups will be under treatment with COVID-19 national standard protocol. In one group in addition to standard treatment, oral Atorvastatin 40 mg will be prescribed for 5 days and other group will only receive standard care.

Main outcome variables

Mortality; Hospital discharge; C-Reactive Protein level; duration of hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190727044343N2**

Registration date: **2020-04-19, 1399/01/31**

Registration timing: **retrospective**

Last update: **2020-04-19, 1399/01/31**

Update count: **0**

Registration date

2020-04-19, 1399/01/31

Registrant information

Name

Lotfollah Davoodi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 4221 8231

Email address

lotfdavoodi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-05, 1399/01/17

Expected recruitment end date

2020-04-13, 1399/01/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Atorvastatin effect in Clinical and Laboratory findings of patients with COVID-19 admitted RAZI referral hospital in Mazandaran State: A Randomized Clinical Trial

Public title

Atorvastatin effect on COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmed COVID-19 Diagnosis No prior Cardiovascular Disease No history of Statins use Chloroquine use No prior Kaletra usage No prior liver damage No prior myositis

Exclusion criteria:

Prior Kaletra Use Cardiovascular Disease Prior myositis Prior Liver damage

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked Randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Researcher is not aware of which patient will get Atorvastatin and drug will be given by nurse. Patients entry will be in order to admission time and randomly.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Moallem

City

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Province

Mazandaran

Postal code

4817844718

Approval date

2020-04-04, 1399/01/16

Ethics committee reference number

IR.MAZUMS.REC.1399.042

Health conditions studied

1

Description of health condition studied

Coronavirus Disease 2019 (COVID-19)

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes

1

Description

CRP level in Blood

Timepoint

At the beginning of the study at after 5 consecutive days

Method of measurement

Blood sampling and CRP measuring

Secondary outcomes

1

Description

Mortality during the study

Timepoint

from the beginning of the study until discharge

Method of measurement

Observing

2

Description

Duration of recovery

Timepoint

From the beginning of the study until discharge

Method of measurement

Observing and case file review

Intervention groups

1

Description

Intervention group: Oral Atorvastatin 40 mg for 5 days

Category

Treatment - Drugs

2

Description

Control group: Routine Care

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Coronavirus center

Full name of responsible person

Lotfollah Davoodi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Street address

Vice Chancellery for Research and Technology of
Mazandaran University of Medical Sciences, Moallem
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research@mazums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Lotfollah Davoodi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Demographic data and data related to final outcome will be shared by maintaining confidentiality.

When the data will become available and for how long

6 months after end of study

To whom data/document is available

Clinical Researchers and Healthcare workers

Under which criteria data/document could be used

Data can be used to re-analyze and in order to modify guidelines and further research on this drug.

From where data/document is obtainable

To Director in Charge of the project; Dr. Lotfollah Davoodi

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

Request will be reviewed by Director in Charge and in case of eligibility, it would be shared in two weeks.

Comments