

# 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

Sari

## 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

**Street address**

Amirmazandarani

**City**

Sari

**Province**

Mazandaran

**Postal code**

4816633131

**Phone**

+98 11 3336 1700

**Fax****Email**

lotfdavoodi@yahoo.com

## 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  
Square

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**Postal code**

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**Phone**

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**Email**

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

**Street address**

Razi hospital

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Lotfdavoodi@yahoo.com

## Person responsible for scientific 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

### 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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**Email**

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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**