Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Atorvastatin effect in Clinical and Laboratory findings of patiens 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 patiens 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 Sceinces
Full name of responsible person
Majid Saeedi
Street address
Vice Chancellery for Research and Technology of Mazandaran University of Medical Sciences, Moallem Square
City
Sari
Province
Mazandaran
Postal code
4817844718
Phone
+98 11 3325 7230
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 Sceinces
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
City
Sari
Province
Mazandaran
Postal code
4817844718
Phone
+98 11 4221 8231
Fax
Email
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
Street address
Ghaemshahr Razi Hospital
City
Sari
Province
Mazandaran
Postal code
4817844718
Phone
+98 11 4221 8231
Email

lotfdavoodi@yahoo.com

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

Street address
Razi

City
Qaemshahr

Province
Mazandaran

Postal code
4765686743

Phone
+98 11 4221 8231

Email
lotfdavoodi@yahoo.com

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 bee 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