Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Prognostic Efficacy of Moderate Intensity rosuvastatin on the Infected cases with SARS-Cov-2

Protocol summary

Study aim
we designed an open-label clinical trial to investigate the prognostic efficacy of moderate-intensity rosuvastatin therapy in individuals infected with SARS-CoV-2. By evaluating key clinical endpoints such as disease severity, progression to severe complications, and mortality, we aim to provide valuable insights into the role of rosuvastatin in the management of COVID-19.

Design
Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct
An interventional study conducted on 100 patients hospitalized with COVID-19. In this study, patients were randomly assigned into case and intervention group, all participants were prescribed standard treatment regimen. In the intervention group, patients were commenced on rosuvastatin at dose of 10 mg once daily for two weeks as add-on standard care.

Participants/Inclusion and exclusion criteria
The inclusion criteria included patients who were not currently taking statin treatment and had a confirmed diagnosis of COVID-19 based on imaging or PCR results. The exclusion criteria included patients with known liver disease, cirrhosis, autoimmune hepatitis, chronic viral hepatitis, rhabdomyolysis myopathy, severe kidney disease, a history of statin sensitivity, and higher-than-normal ALT and CPK in the initial test. Patients who had previously taken statins at different dosages as well as women who were pregnant or nursing were not included. If the patient developed symptoms of hepatitis or myopathy, muscle weakness and increased liver and muscle enzymes after taking statin, the drug was discontinued and the patient was excluded from the study.

Intervention groups
10 mg of rosuvastatin

Main outcome variables
disease severity, progression to severe complications, and mortality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230722058883N2**
Registration date: **2024-03-01, 1402/12/11**
Registration timing: **retrospective**

Last update: **2024-03-01, 1402/12/11**
Update count: **0**

Registration date
2024-03-01, 1402/12/11

Registrant information

Name
Alireza Azarboo

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 902 175 3418

Email address
ar-azarboo@student.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-19, 1399/01/31

Expected recruitment end date
2020-05-20, 1399/02/31

Actual recruitment start date
2020-04-19, 1399/01/31

Actual recruitment end date
2020-05-20, 1399/02/31

Trial completion date

2020-05-20, 1399/02/31

Scientific title

Prognostic Efficacy of Moderate Intensity rosuvastatin on the Infected cases with SARS-Cov-2

Public title

rosuvastatin and SARS-Cov-2

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients who were not currently taking statin treatment patients who had a confirmed diagnosis of COVID-19 based on imaging or PCR results.

Exclusion criteria:

patients with known liver disease, cirrhosis, autoimmune hepatitis, chronic viral hepatitis, rhabdomyolysis myopathy, severe kidney disease, a history of statin sensitivity, and higher-than-normal ALT and CPK in the initial test. Patients who had previously taken statins at different dosages as well as women who were pregnant or nursing If the patient developed symptoms of hepatitis or myopathy, muscle weakness and increased liver and muscle enzymes after taking statin

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

COVID-19 patients hospitalized on double beds were considered as the case group, 10 mg rosuvastatin in addition to the inpatient treatment protocol (hydroxychloroquine and atazanavir). However, the patients who were hospitalized in individual beds were randomly assigned to the control group, treated only with the inpatient protocol (hydroxychloroquine and atazanavir) (control group). Block randomization In order to minimize distortions, we plan to allocate eligible patients to two groups receiving rosuvastatin in addition to the inpatient treatment protocol (hydroxychloroquine and atazanavir) (intervention (A) and receiving the only inpatient treatment protocol (hydroxychloroquine) by the block random assignment method chloroquine and atazanavir) (intervention B), we divide each group with a population of 50 people. 1- The number of patients in each block: since we have two types of interventions, we consider the number of patients in each block to be 4 (double the number of interventions). If we determine the number of patients in each block to be less or more, they are similar to sequential randomization and simple randomization, which are associated with distortions. 2- The number of required blocks: Since the sample size is calculated to be 100 people and the number of patients in each block is 4, we need 25 blocks. 3- Types of blocks: Since the number of patients in each block is 4 (Bc) and the number of types of interventions (Tn) is two, we have 6 types of blocks using the formula below. We randomly assigned a number to each type of block. 1.AABB 2.ABAB 3.ABBA 4.BABA 5.BBAA 6.BAAB 4- The maximum number of repetitions allowed to select each block: since the number of required blocks is more than the number of types of blocks, we have to use each block more than once. To reduce torsion, the best possible situation is to use 2 types of blocks 4 times and other blocks 3 times. 5- Random selection of the type of blocks: At first, using the minitab statistical software and setting the base set equal to 1 and the random data section of the software, blocks 1 and 4, which are supposed to be used 4 times, were randomly selected. Then again, using set base equal to 1, we reached the following random sequence from left to right: 1-4-4-6-2-6-1-2-1-4-5-5-3-4-3-6-1-3-2-5 6- Random selection of the block sequence: to each of the blocks selected in the previous section, we assign the numbers 1 to 20 in order from left to right.) then using the minitab statistical software and setting the base set equal to 1, we get the following random sequence of numbers from 1 to 20:
7-4-18-19-17-13-9-12-14-5-2-11-20-3-6-8-15-1-10-16
Thus, the final sequence of blocks is as follows:
1-6-3-2-1-3-1-5-4-2-4-5-5-4-6-2-3-1-4-6 7- The final sequence of interventions: taking into account the final sequence obtained in the previous section and that each number represents the sequence of interventions (section 3), we implement the interventions in the following order from left to right in eligible patients: AABB, BAAB, ABBA, ABAB, AABB, ABBA, AABB, BBAA, BABA, ABAB, BABA, BBAA, BBAA, BABA, BAAB, ABAB, ABBA, AABB, BABA, BAAB In other words, the first patient received rosuvastatin in addition to the inpatient treatment protocol (hydroxychloroquine and atazanavir), the second patient received rosuvastatin in addition to the inpatient treatment protocol (hydroxychloroquine and atazanavir), the third patient received only the inpatient treatment protocol (hydroxychloroquine and atazanavir) and... they do.

Blinding (investigator's opinion)

Double blinded

Blinding description

This was a double-blind trial, meaning the questionnaires of patients in the intervention and control group were coded, and then randomly selected according to the number of the hospitalized bed, and during the follow-up time at one month later, neither the researcher nor the patient was informed of the content of the injection.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Vice-Chancellor in Research Affairs- Tehran University of Medical Scie

Street address
End of Keshavarz Boulevard

City
Tehran

Province
Tehran

Postal code
1419733141

Approval date
2020-04-05, 1399/01/17

Ethics committee reference number
IR.TUMS.VCR.REC.1399.133

Health conditions studied

1

Description of health condition studied
The health condition studied in "Prognostic Efficacy of Moderate Intensity rosuvastatin on the Infected cases with SARS-Cov-2" pertains to individuals diagnosed with COVID-19, the disease caused by the novel coronavirus SARS-CoV-2. COVID-19 manifests with a spectrum of clinical presentations ranging from asymptomatic or mild respiratory symptoms to severe pneumonia, acute respiratory distress syndrome (ARDS), and multiorgan dysfunction. This study focuses on evaluating the prognostic efficacy of moderate-intensity rosuvastatin therapy in COVID-19 patients, with a particular emphasis on disease severity, progression to severe complications, and mortality. By investigating the impact of rosuvastatin on clinical outcomes in individuals infected with SARS-CoV-2, the study aims to contribute valuable insights into the potential role of statins as adjunctive therapy in managing COVID-19 and improving patient outcomes.

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
The severity of disease was evaluated based on the following variables: the temperature measured by thermometer and arterial oxygen saturation measured by pulse oximeter; observation of vital signs including heart and respiratory rate on the first day of hospitalization and the day of discharge; CBC-related information including the level of CRP, ESR, WBC, Plt, ALT and CPK at the beginning of hospitalization and on the day of discharge; length of hospitalization as well as the need for ICU and intubation; shortness of breath assessed based on the Borg questionnaire and cough based on the LCQ questionnaire on the first day and at the time of discharge and after two weeks of statin administration (evaluated by phone call); and lastly, one-month mortality in cases and controls.

Timepoint
on the first day and at the time of discharge and after two weeks and 1 month of statin administration

Method of measurement
thermometer, pulse oximeter, CBC, Borg questionnaire and LCQ questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 10 mg of rosuvastatin in addition to the inpatient protocol treatment (hydroxychloroquine and atazanavir)

Category
Treatment - Drugs

2

Description
Control group: only the treatment of the inpatient protocol (hydroxychloroquine and atazanavir)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital

Full name of responsible person
Samaneh Parsa

Street address
End of Keshavarz Boulevard

City
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6119 0000

Email
samaneh_parsa@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Samaneh Parsa
Street address
End of Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Email
samaneh_parsa@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Samaneh Parsa
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
End of Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Email
samaneh_parsa@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Samaneh Parsa
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
End of Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Email
samaneh_parsa@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Samaneh Parsa
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
End of Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Email
samaneh_parsa@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available