

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Efficacy of Atorvastatin on 90 patients in-hospital outcome of COVID-19 infection in boali hospital of Qazvin

Protocol summary

Study aim

Comparison of placebo and atorvastatin in improving clinical and laboratory symptoms of hospitalized patients with COVID-19

Design

The study will be conducted as a randomized controlled double-blind clinical trial. 90 patients with coronary infection (confirmed by CT or PCR) will be divided into selected atorvastatin 40 mg tablets once a day in selected hospitals of Qazvin and the control group will receive placebo for 7 days. The obtained results will be analyzed by SPSS software version 25. The quantitative variables will be presented as median \pm SD

Settings and conduct

This study will be performed on 90 patients admitted with clinical or paraclinical diagnosis of Covid-19. Based on these criteria, randomly selected patients will be divided into two approximately equal groups. The randomization method will be using random number generation software

Participants/Inclusion and exclusion criteria

Hospitalization in corona-related wards Confirmation of the disease by CT scan or PCR No history of liver failure

Intervention groups

They will be divided into two groups receiving atorvastatin 40 mg tablets once a day and the control group receiving placebo for 7 days.

Main outcome variables

Duration of hospitalization; Blood oxygen(sa o₂); Intubation; Mortality rate; need of icu

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200906048638N1**

Registration date: **2021-02-01, 1399/11/13**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-01, 1399/11/13**

Update count: **0**

Registration date

2021-02-01, 1399/11/13

Registrant information

Name

rozita bahadori

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 3036

Email address

bahadorirozana@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-04-19, 1400/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Atorvastatin on 90 patients in-hospital outcome of COVID-19 infection in boali hospital of Qazvin

Public title

Efficacy of Atorvastatin on in-hospital outcome of COVID-19 infection

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Hospitalization in corona-related wards Confirmation of the disease by CT scan or PCR No history of liver failure

Exclusion criteria:

Having non-pulmonary fungal and bacterial infections (non-pulmonary, infectious bed sores, etc.) Lack of patient consent to participate in the study Receive treatments other than chloroquine, azithromycin and ceftriaxone History of receiving statins Hypersensitivity reaction or any contraindication to the use of atorvastatin

Age

No age limit

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In this trial, random sequence generation software was used for randomization. In this way, information such as sample size and number of groups is given to the software and the software provides a table of random numbers, each of which is randomly assigned the letters A and B. The output of the male is a table, in which 90 people are randomly placed in groups A and B.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients included in the study did not know how to give placebo and the main drug, and only how to work and obtain consent to participate in the study were explained to them.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

naderi,boalisina hospital

City

qazvin

Province

Qazvin

Postal code

3413786167

Approval date

2020-08-15, 1399/05/25

Ethics committee reference number

ir.qums.rec.1399.171

Health conditions studied

1

Description of health condition studied

coronavirus/ststin

ICD-10 code

U07.1

ICD-10 code description

Clinically-epidemiologically diagnosed COVID-19

Primary outcomes

1

Description

crp

Timepoint

the first, third, fifth day

Method of measurement

questionnaire

2

Description

wbc

Timepoint

the first, third, fifth day

Method of measurement

questionnaire

3

Description

fever

Timepoint

the first, third, fifth day

Method of measurement

questionnaire

4

Description

tachikardia

Timepoint

the first, third, fifth day

Method of measurement

questionnaire

5

Description

heart rate

Timepoint

the first, third, fifth day

Method of measurement

questionnaire

6**Description**

bp

Timepoint

the first, third, fifth day

Method of measurement

questionnaire

7**Description**

sa o2

Timepoint

the first, third, fifth day

Method of measurement

questionnaire

8**Description**

bs

Timepoint

the first, third, fifth day

Method of measurement

questionnaire

9**Description**

plt

Timepoint

the first, third, fifth day

Method of measurement

questionnaire

Secondary outcomes**1****Description**

Quality of life score

Timepoint

The first, third and fifth day

Method of measurement

questionnaire

Intervention groups**1****Description**

Intervention group:atrovastatin 40 mg tablets once a day for 7 days abidi company

Category

Treatment - Drugs

2**Description**

Control group:plasibo once a day for 7 days porsina company

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

bualisina hospital of qazvin

Full name of responsible person

abaas allami

Street address

Naderi,bualisina hospital

City

Qazvin

Province

Qazvin

Postal code

3413786165

Phone

+98 28 3333 2930

Email

Allami9@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

mahnaz abbasi

Street address

pardis Complex of Qazvin University of Medical Sciences - Shahid Babaei Medical School, second floor, room number 201

City

Qazvin

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3413786165

Phone

+98 28 3323 9252

Email

mabasi@qums.ac.ir

Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Qazvin University of Medical Sciences

Proportion provided by this source

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**

Qazvin University of Medical Sciences

Full name of responsible person

abass allami

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Email

Allami9@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

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

Title and more details about the data/document

If the Vice Chancellor of the University agrees, all data can be shared after identifying individuals

When the data will become available and for how long

From 6 months after printing the results

To whom data/document is available

If the Vice Chancellor of the University agrees, at the request of another researcher to metanize the arrest set, acceptable data will be provided to another researcher.

Under which criteria data/document could be used

If the Vice Chancellor of the University agrees, at the request of another researcher to metanize the arrest set, acceptable data will be provided to another researcher.

From where data/document is obtainable

If the Vice Chancellor of the University agrees, at the request of another researcher to metanize the arrest set,

acceptable data will be provided to another researcher.
What processes are involved for a request to access data/document

If the Vice Chancellor of the University agrees, at the

request of another researcher to metanize the arrest set,
acceptable data will be provided to another researcher.
Comments