

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Sep 2021

Effect of atorvastatin on mortality rate and symptom improvement in hospitalized patients with COVID-19

Protocol summary

Study aim

Effect of atorvastatin on mortality rate and symptom improvement in hospitalized patients with COVID-19

Design

A randomized, clinical trial with a parallel group design of 80 patients in each group (totally 160 patients), and followed till they are hospitalized. Randomization will be done with computer.

Settings and conduct

In this study the effect of atorvastatin on mortality rate and symptom improvement in hospitalized patients with COVID-19 are going to be evaluated. COVID-19 infected people who are inpatients in Emam Hassan Hospital, Bojnourd are randomized into control or intervention group. Control group: Hydroxychloroquine and Kaletra treatment according to the national guideline for the treatment of COVID-19 Intervention group: Hydroxychloroquine and Kaletra treatment according to the national guideline for the treatment of COVID-19 and Atorvastatin, 1 tablet, 20 mg, daily, during hospitalization

Participants/Inclusion and exclusion criteria

COVID-19 infected patients who are inpatients in the hospital and are treated with Kaletra and Hydroxychloroquine. these patients have no underlying diseases and have no need to I.C.U when are registered in this study.

Intervention groups

Control group: Hydroxychloroquine and Kaletra treatment according to the national guideline for the treatment of COVID-19, during hospitalization
Intervention group: Hydroxychloroquine and Kaletra treatment according to the national guideline for the treatment of COVID-19 and Atorvastatin, 1 tablet, 20 mg, daily, during hospitalization

Main outcome variables

Duration of stay at hospital; mortality rate; indication for Intubation; duration of intubation; duration of improvement in clinical sign and symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190831044653N5**

Registration date: **2020-08-24, 1399/06/03**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-24, 1399/06/03**

Update count: **0**

Registration date

2020-08-24, 1399/06/03

Registrant information

Name

Maryam Rameshrad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3229 7182

Email address

rameshrm2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-20, 1399/05/30

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of atorvastatin on mortality rate and symptom improvement in hospitalized patients with COVID-19

Public title

The effect of Atorvastatin therapy in COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

COVID-19 infected people who are inpatient in the hospital

Exclusion criteria:

type 1 diabetes ketoacidosis Uncompensated heart failure sever renal failure GFR<30ml/min metabolic acidosis structural respiratory dysfunction Indications for Intubation at the registering time to the hospital

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted Block Randomization will be used. At first, the block size is considered 4. Then, the possible ways to equally assign participants to a block will be written for 160 subjects. (AABB(1)- ABAB(2)-ABBA(3)-BBAA(4)-BABA(5)-...- BAAB(n)). After that, numbers between 1-n will be chosen randomly from the table of random numbers which shows the ordinary of the blocks for participating in the study.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of North Khorasan University of Medical Sciences

Street address

Shahryar

City

Bojnurd

Province

North Khorasan

Postal code

9417694786

Approval date

2020-05-04, 1399/02/15

Ethics committee reference number

IR.NKUMS.REC.1399.035

Health conditions studied**1****Description of health condition studied**

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes**1****Description**

hospitalization

Timepoint

end of study

Method of measurement

Patient file in the hospital

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

mortality rate

Timepoint

end of study

Method of measurement

Patient file in the hospital

2**Description**

intubation indication

Timepoint

end of study

Method of measurement

Patient file in the hospital

3**Description**

duration of intubation

Timepoint

end of study

Method of measurement

Patient file in the hospital

4

Description

duration of sign and symptoms (fever, cough ,...)

Timepoint

daily

Method of measurement

Patient file in the hospital and questionnaire

Intervention groups

1

Description

Intervention group: Hydroxychloroquine and Kaletra treatment according to the national guideline for the treatment of COVID-19 and Atorvastatin, 1 tablet, 20 mg, daily, during hospitalization

Category

Treatment - Drugs

2

Description

Control group: Hydroxychloroquine and Kaletra treatment according to the national guideline for the treatment of COVID-19, during hospitalization

Category

Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Emem Hasan hospital

Full name of responsible person

Dr. Majid Ghafoori

Street address

Shahriar

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Bojnourd University of Medical Sciences

Full name of responsible person

dr. seyed Kaveh Hojat

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S.Kavehhojjat1@gmail.com

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

Yes

Title of funding source

Bojnourd 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**

Bojnourd University of Medical Sciences

Full name of responsible person

Majid Ghafoori

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Majid Ghafoori

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Maryam Rameshrad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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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

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

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