

# 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, Bojnord 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

**City**

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**Province**

North Khorasan

**Postal code**

9417694786

**Phone**

+98 58 3229 7182

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**Email**

ghafourim841@yahoo.com

### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Bojnourd University of Medical Sciences

**Full name of responsible person**

dr. seyed Kaveh Hojat

**Street address**

Shahriar

**City**

Bojnurd

**Province**

North Khorasan

**Postal code**

9414974877

**Phone**

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**Email**

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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Shahriar street,

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## Person responsible for scientific 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**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Bojnourd University of Medical Sciences

**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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**Email**

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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