Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluating the efficacy of Atorvastatin in clinical improvement, prognosis and hospitalization course in patients with COVID-19 infection

Protocol summary

Study aim
Evaluation the efficacy and safety of Atorvastatin as adjutant therapy in hospitalized patients with COVID-19 infection

Design
The study is a non-randomized, single-blind clinical trial

Settings and conduct
Clinical trials will be conducted at the Bu Ali Hospital affiliated to Islamic azad university Tehran Medical Sciences on hospitalized COVID-19 patients. Patients are treated in intervention and control groups. The study will be performed at the beginning of patient hospitalization. At the end of the study results will be presented to analyzer in two blinded groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Older than 18 years old, Hospitalized with COVID-19 infection and signed the informed consent Exclusion criteria: Pregnancy, lactation, history of allergy to atorvastatin. Presence of other contraindications, Enrollment in another clinical study

Intervention groups
Control group: only standard drug therapy for coronavirus recommended by local national guideline will be received. intervention group: This group adjunct to standard treatment will receive Atorvastatin 20 mg orally once daily

Main outcome variables
Clinical response, Laboratory response. Rate of adverse drug reactions, Rate of complications secondary to COVID-19 infection, Duration of hospital stay

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200413047062N1**
Registration date: **2020-05-04, 1399/02/15**
Registration timing: **registered_while_recruiting**
Last update: **2020-05-04, 1399/02/15**
Update count: **0**

Registration date
2020-05-04, 1399/02/15

Registrant information

Name
Hamid Reza Moezi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 3334 8040

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hmoezi@iautmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-13, 1399/01/25

Expected recruitment end date
2020-05-14, 1399/02/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the efficacy of Atorvastatin in clinical improvement, prognosis and hospitalization course in patients with COVID-19 infection

Public title
Effect of Atorvastatin in treatment of COVID-19 infection

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients age over 18 years Hospitalized with diagnosis of COVID-19 infection

Exclusion criteria:

Pregnancy Lactation History of hypersensitivity reaction to atorvastatin, Liver dysfunction (Liver enzymes > 3 ULN or bilirubin >2 ULN or history of liver failure) Renal failure (eGFR < 30ml/min), History of major side effects with statins (such as liver toxicity, rhabdomyolysis) Patients are receiving other drugs which have major interaction (such as Gemfibrozil, cyclosporine, amiodarone, itraconazole, variconazole, clarithromycin) LDL Level below than 40 mg/dl Involvement in another clinical study

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, after receiving informed consent from of both control and intervention groups, all oral medications of both group are administered in boxes with different codes, as a result, the patient is unaware that he or she has been received atorvastatin in addition to other medications and they kept blind. also, the researcher who will analyze the data will be blind using codes for different groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University Of Pharmaceutical Sciences Branch

Street address

Yakhchal Avenue، Qolhak، Dotor Shariati Avenue

City

Tehran

Province

Tehran

Postal code

193956466

Approval date

2020-04-12, 1399/01/24

Ethics committee reference number

IR.IAU.PS.REC.1399.002

Health conditions studied

1

Description of health condition studied

COVID-19 infection

ICD-10 code

U07.1

ICD-10 code description

COVID-19 has been confirmed by laboratory testing

Primary outcomes

1

Description

Time to clinical improvement (TTIC)

Timepoint

Daily

Method of measurement

Based on clinical findings such as fever, respiratory rate, percentage of oxygen saturation, cough

2

Description

Duration of hospitalization

Timepoint

End of the treatment

Method of measurement

Patient's record

3

Description

Adverse effects

Timepoint

Daily

Method of measurement

Interview and patient's record

4

Description

Clinical outcome (cure or death)

Timepoint

End of the treatment

Method of measurement

Patient's record

Secondary outcomes

1

Description
need for ICU admission
Timepoint
Daily
Method of measurement
Patient's record

2

Description
Need for Mechanical ventilation
Timepoint
Daily
Method of measurement
Interview and patient's record

3

Description
Change in radiologic findings
Timepoint
End of the treatment
Method of measurement
Patient's record

4

Description
The change in inflammatory markers
Timepoint
daily
Method of measurement
Patient's record

Intervention groups

1

Description
Intervention group: Concomitant with the national corona treatment recommendation + Atorvastatin 20 mg daily for full course of therapy
Category
Treatment - Drugs

2

Description
Control group: Only national corona treatment recommendation
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bu Ali hospital
Full name of responsible person
Hamidreza Moezi
Street address
Bu Ali hospital, Imam Hossein sq. Damavand Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Farshad Hashemian
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Shariati Avenue, Yakhchal Street,Tehran
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hashemian.f@iaups.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
Hamidreza Moezi

Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Tehran University of Medical Sciences
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Resident of Clinical pharmacy (BCPS)
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
Title and more details about the data/document
Results of the study will be published. The study protocol and statistical analysis will be included in the manuscript
When the data will become available and for how long
up to One year after finishing the study, data will be published and will be available in databases
To whom data/document is available
After permission form the sponsor, data of the study will be available for academic researchers, physicians and scientific institutes
Under which criteria data/document could be used
Other researchers are permitted to included the results in their reviews and meta-analysis
From where data/document is obtainable
contact with Dr hamidreza moezi at school of medicine, Islamic Azad University, Tehran Medical Branch
What processes are involved for a request to access data/document
After receiving the query, dependent on the requested data, the scientific responsible person of the study will response to the query in coordinate with the sponsor within 2 weeks
Comments