

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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 adjunctant 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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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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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

Internal Medicine

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Person responsible for scientific inquiries

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Tehran University of Medical Sciences

Full name of responsible person

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Position

Resident of Clinical pharmacy (BCPS)

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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Full name of responsible person

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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