

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the efficacy of Atorvastatin in the management of critically ill COVID-19 patients: A Randomized-controlled clinical trial

Protocol summary

Study aim

1. Determining and comparison of the number of patients with clinical improvement and treatment failure at the end of the fifth, tenth, and fourteenth days of intervention, between study groups (the experimental and control groups) 2. Determining and Comparison of the mean CRP and IL-6 at the end of the fifth, tenth, and fourteenth days of intervention, between study groups (the experimental and control groups) 3. Determining and comparison of the number of intubated patients between study groups (the experimental and control groups) at the end of the study

Design

Two arms parallel-group randomized trial with control group design of 60 patients, phase 3. Block randomization was carried out by computer.

Settings and conduct

This study will be a randomized -controlled clinical trial to evaluate the effectiveness of atorvastatin in the treatment of Covid patients admitted to the intensive care unit of eligible hospitals for hospitalized Covid-19 patients affiliated to Isfahan University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 years or older Diagnosis of COVID-19 Hospitalization in the intensive care unit Full consent and acceptance of the patient or their legal guardian to recruit in the study Possibility to follow the patient for at least seven days Exclusion criteria: Contraindications of atorvastatin administration Malignancy or immune deficiency Patients under mechanical ventilation

Intervention groups

Intervention group: In addition to the essential treatment for COVID-19, one tablet of atorvastatin 20 mg daily will be administered for 14 days. Control group: Standard and essential treatment for COVID-19

Main outcome variables

Clinical improvement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150221021159N7**

Registration date: **2021-11-10, 1400/08/19**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-10, 1400/08/19**

Update count: **0**

Registration date

2021-11-10, 1400/08/19

Registrant information

Name

Shadi Farsaei

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 2618

Email address

farsaei@pharm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of Atorvastatin in the management of critically ill COVID-19 patients: A Randomized-controlled clinical trial

Public title

Effect of Atorvastatin in the management of COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 years or older
Diagnosis of COVID-19 by RT PCR test and CT scan of the lung and the opinion of the specialist physician
Hospitalization in the intensive care unit
Full consent and acceptance of the patient or their legal guardian to recruit in the study
Possibility to follow the patient for at least 7 days

Exclusion criteria:

Contraindications to the use of atorvastatin include allergic reactions to the drug, active liver disease or persistent and unexplained increase in liver enzymes, pregnancy and lactation, severe hepatic or renal insufficiency (clcr <30 ml / min)
Malignancy or underlying immunodeficiency or concomitant use of immunosuppressive drugs
Intubated patient under care with mechanical ventilation

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization with the permuted block method was used to create the random sequence in each group. At first, the specific internet software (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>) was used to create the random series in blocks of 2, 4, and 6. Each block has an equal number of melatonin and control groups. After that, created codes were written on the cards and placed respectively for hiding in locked opaque packets. A packet was selected for each patient according to the study recruitment, which determines the related study group.

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 Isfahan University of Medical Sciences

Street address

Department of clinical pharmacy and pharmacy practice, faculty of pharmacy, Isfahan University of Medical Sciences, Hezar Jarib Ave. Isfahan University of Medical Sciences.

City

Isfahan

Province

Isfahan

Postal code

۷۳۴۶۱-۸۱۷۴۶

Approval date

2021-09-19, 1400/06/28

Ethics committee reference number

IR.MUI.MED.REC.1400.492

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Clinical improvement of COVID-19

Timepoint

Day: 1, 3, 7 and 14

Method of measurement

APACHE score, evaluation of vital signs, relevant laboratory and arterial blood gas analysis.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to the essential and standard treatment for COVID-19, one tablet of atorvastatin 20 mg (Abidi pharmaceutical company), once daily will be administered for 14 days.

Category

Treatment - Drugs

2

Description

Control group: Standard and essential treatment for COVID-19

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Shadi Farsaei

Street address

Sofeh Boulevard - Al-Zahra Educational and Medical Center

City

Esfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3792 7071

Fax

Email

farsaei@pharm.mui.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjou Javanmard

Street address

Hezar Jerib St., Isfahan University of Medical Sciences and Health Services, Central Headquarters

City

Esfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 8138

Email

research@mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Shadi Farsaei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Clinical pharmacy and pharmaceutical practices department, Pharmacy faculty, Isfahan university of medical sciences, Hezar jerib Ave., Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 7071

Email

Farsaei@pharm.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shadi Farsaei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Clinical pharmacy and pharmaceutical practices department, Pharmacy faculty, Isfahan university of medical sciences, Hezar jerib Ave., Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 7071

Email

Farsaei@pharm.mui.ac.ir

Postal code

8174673461

Phone

+98 31 3792 7071

Email

Farsaei@pharm.mui.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Shadi Farsaei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Clinical pharmacy and pharmaceutical practices department, Pharmacy faculty, Isfahan university of medical sciences, Hezarjerib St.

City

Isfahan

Province

Isfahan

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

Not applicable