

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Effect of Atorvastatin to decrease intensity of clinical manifestations in patient with COVID19

Protocol summary

hospitalization, Length of ICU stay, Releasing or death

Study aim

Effect of Atorvastatin to decrease intensity of clinical manifestations in patient with COVID19

Design

Clinical trial with control group and parallel groups, double blind, with using a permuted balanced block randomization method with the size of blocks 4 and 6, phase 3 on 100 patients, Random sequence will be generated by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>).

Settings and conduct

The aim of this study is evaluation of Atorvastatin effect in reducing clinical manifestation of COVID19. Locality of the study is in Amiralmomenin and Khansari hospital of Arak city. In Atorvastatin group, Atorvastatin 40 mg tablet orally (or with gavage in intubated patients) will be added to routine treatment protocol for 10 days from first day and in control group flour tablet that is similar to Atorvastatin will be given to the patients (in addition to routine treatment) for 10 days from first day, too.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with 18 to 75 years old Positive PCR for COVID19 in patients who refer to Amiralmomenin and Khansari hospital of Arak city Having the informed consent Non-inclusion criteria: long time use of Statins Pregnancy and lactation History of sensitivity to Statins Chronic renal failure long time treating with Colchicine, Cyclosporine, Digoxin, Azole antifungal agents, Niacin

Intervention groups

In Atorvastatin group, Atorvastatin 40 mg tablet for 10 days from first day will be added to routine treatment protocol and in control group flour tablet that is similar to Atorvastatin will be given to the patients (in addition to routine treatment).

Main outcome variables

Duration of having fever, Duration of having cough, Atrial oxygen saturation, Duration of intubation, Duration of invasive or non invasive oxygen therapy, Length of

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201028049175N3**

Registration date: **2021-01-15, 1399/10/26**

Registration timing: **prospective**

Last update: **2021-01-15, 1399/10/26**

Update count: **0**

Registration date

2021-01-15, 1399/10/26

Registrant information

Name

Shamim Valibak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3502

Email address

sh.valibak@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Atorvastatin to decrease intensity of clinical manifestations in patient with COVID19

Public title

Effect of Atorvastatin to decrease intensity of clinical manifestations in patient with COVID19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with 18-75 years old Patients with positive PCR test for COVID19 who ara referred to Amiralmomenin and Khansari hospitals of Arak city Patients who have informed consent for entrance into the study.

Exclusion criteria:

Pregnancy and lactation

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated into two groups using a permuted balanced block randomization method with the size of blocks 4 and 6. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Concealment is also guaranteed due to the use of permuted balanced block randomization method.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients blindness: Both kinds of tablets(Atorvastatin and flour tablet) are similar in shape and time of use. Nurses blindness: Preparation and appropriation of drugs will be accomplished by the physician.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Assistance of research and technology, Payambare azam institution, Arak University of Medical Sciences, Basij square

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2020-11-29, 1399/09/09

Ethics committee reference number

IR.ARAKMU.REC.1399.257

Health conditions studied

1

Description of health condition studied

Coronavirus Disease 2019 (COVID19)

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Duration of having fever

Timepoint

Measurement of body temperature daily from first day to releasing day

Method of measurement

Thermometer

2

Description

Duration of having cough

Timepoint

Daily evaluation of having cough from first day to releasing day

Method of measurement

Quastion of patient or his carer

3

Description

Atrial oxygen saturation in hospital

Timepoint

Daily evaluation from first day to releasing day

Method of measurement

Pulse oximeter

4

Description

Length of hospitalization

Timepoint

From first day of hospitalization to releasing day

Method of measurement

patient file

5

Description

Length of ICU stay

Timepoint

From first day of hospitalization to releasing day

Method of measurement

patient file

6

Description

Duration of intubation

Timepoint

From first day of hospitalization to releasing day

Method of measurement

patient file

7

Description

Mortality

Timepoint

From first day of hospitalization to releasing day

Method of measurement

patient file

8

Description

Duration of oxygen therapy

Timepoint

From first day of hospitalization to releasing day

Method of measurement

Patient file

Secondary outcomes

1

Description

White blood cell count

Timepoint

From first day of hospitalization to releasing day

Method of measurement

patient file

2

Description

lymphocyte percentage

Timepoint

From first day of hospitalization to releasing day

Method of measurement

patient file

3

Description

Lactate dehydrogenase level

Timepoint

From first day of hospitalization to releasing day

Method of measurement

patient file

4

Description

Creatine phosphokinase level

Timepoint

From first day of hospitalization to releasing day

Method of measurement

patient file

Intervention groups

1

Description

Intervention group: Atorvastatin 40 mg tablet orally (or with gavage in intubated patients) will be added to routine treatment protocol for 10 days from first day of hospitalization.

Category

Treatment - Drugs

2

Description

Control group: Placebo drug (flour tablet) which is similar to Atorvastatin in its shape and size will be given to the patients for 10 days from first day of hospitalization (in addition to routine treatment).

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Khansari hospital

Full name of responsible person

Masumeh Soofian

Street address

The end of Daneshgah street

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Email

2**Recruitment center****Name of recruitment center**

Amiralmomenin hospital

Full name of responsible person

Behnam mahmoodieh

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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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

Arak 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****Person responsible for general inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Position

lecturer

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Masumeh Soofian

Position

Professor

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Specialist

Other areas of specialty/work

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

Arak University of Medical Sciences

Full name of responsible person

shamim valibak

Position

General physician non-faculty

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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