Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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

Design
Clinichal 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 evalution 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 loctation 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 hospitalization, Length of ICU stay, Releasing or death

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)

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+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
Measuement 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 hospitaliztion
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
City
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3818649433
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Email

research@arakmu.ac.ir

2

Recruitment center

Name of recruitment center
Amiralmomenin hospital

Full name of responsible person
Behnam mahmoodieh

Street address
Amiralmomenin hospital street, Basij square

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it-amiralmomenin@arakmu.ac.ir

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

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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
Academic

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

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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
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Medical doctor
Other areas of specialty/work
General Practitioner
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Valiasr hospital, Valiasr square
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sh.valibak@yahoo.com

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