Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Evaluation of atorvastatin tablet efficacy as an adjuvant treatment for patients with mild to moderate COVID-19 in Qaem Hospital, Mashhad: A double-blind randomized placebo controlled clinical trial

Protocol summary

Study aim
Evaluation of the atorvastatin efficacy as a supplement for treatment of hospitalized mild to moderate COVID-19

Design
This is a randomized triple-blind, parallel group clinical trial on 40 patients with mild to moderate hospitalized covid-19 (20 patients in treatment group and 20 patients in placebo group).

Settings and conduct
This study will perform on 40 patients with clinical or laboratory diagnosis of mild to moderate covid-19 who refer to Quem Hospital, Mashhad, Iran. They whether will received one atorvastatin 40mg tablet daily for 2 weeks in treatment group or one placebo tablet in placebo group.

Participants/Inclusion and exclusion criteria
inclusion criteria: patients with clinical or laboratory diagnosis of mild-moderate COVID-19 and admission indication; age between 18-65 y; sign of written consent exclusion criteria: history of allergy to statins; pregnancy and lactation; active liver disease or LFT rise; ADR occurrence like rhabdomyolysis; severe renal failure (GFR<30 ml/min); indication for intubation or ICU

Intervention groups
Treatment group: one atorvastatin tablet daily for 2 weeks, Control group: one placebo tablet daily for two weeks

Main outcome variables
Treatment group: one colchicine tablet daily for 2 weeks, Control group: one placebo tablet daily for two weeks

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200408046990N3**
Registration date: **2020-07-16, 1399/04/26**
Registration timing: **prospective**

Last update: **2020-07-16, 1399/04/26**
Update count: **0**

Registration date
2020-07-16, 1399/04/26

Registrant information

Name
Sepideh Elyasi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 51 3180 1588
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elyasis@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-21, 1399/04/31

Expected recruitment end date
2020-11-20, 1399/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of atorvastatin tablet efficacy as an adjuvant treatment for patients with mild to moderate COVID-19 in Qaem Hospital, Mashhad: A double-blind randomized placebo controlled clinical trial

Public title
Evaluation of atorvastatin tablet as an adjuvant treatment for patients with mild to moderate COVID-19 in Qaem Hospital, Mashhad
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Laboratory or clinical diagnosis of COVID-19 with admission indication age between 18-65 y sign of the written consent not concomitant use of kaletra or other PIs, cyclosporine, colchicine, ciproterone, danazol, gemfibrozil, potent CYP3A4 inhibitors or inducers like macrolides, CCBs, Azoles, rifampin, phenytoin not using statin before including in the study
Exclusion criteria:
history of allergy to statins pregnancy and lactation active liver disease or rise of LFT during study including in other studies start of PIs ADR occurrence e.g. rhabdomyolysis severe renal failure (GFR<30 ml/min) indication for intubation or ICU not being able to swallow medication
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
With the help of a randomization list provided by randomization.com site, patients will receive code 1 or 2 and will be included in placebo or medication group.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The atorvastatin and placebo tablets will be packaged in identical-looking bottle and delivered to the clinician. Patients who meet the inclusion criteria are selected by clinician to be included in the study, randomly assigned to a drug or placebo group and given a bottle with A or B mark. Patients will be evaluated in the course of treatment by the physician. Data collection and analysis are performed by the medical resident and the clinical pharmacist. All of them will be unaware that A or B is on medication or placebo until the end of the study and data analysis.
Placebo
Used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Qureshi Building, Daneshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
1394491388
Approval date
2020-05-06, 1399/02/17
Ethics committee reference number
IR.MUMS.REC.1399.221

Health conditions studied

1

Description of health condition studied
COVID-19 pneumonia
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
fever
Timepoint
daily
Method of measurement
thermometer

2

Description
clinical response to treatment (including improvement of cough, myalgia, headache, Olfactory and taste disorders)
Timepoint
daily
Method of measurement
based on patients examination and interview

3

Description

radiologic response
Timepoint
two weeks after treatment
Method of measurement
lung CT scan

4

Description
laboratory response
Timepoint
weekly
Method of measurement
assessment of serum level of CRP and CBC diff

5

Description
drug adverse reaction
Timepoint
daily
Method of measurement
patient file and interview

Secondary outcomes

1

Description
duration of hospitalization
Timepoint
end of the treatment
Method of measurement
patients' file

2

Description
patients' clinical outcome
Timepoint
at the of the treatment
Method of measurement
patients' file

Intervention groups

1

Description
Intervention group: one atorvastatin 40mg tablet daily for two weeks
Category
Treatment - Drugs

2

Description
Control group: placebo with same appearance of atorvastatin tablet one daily for 2 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Queam hospital
Full name of responsible person
Sepideh Elyasi
Street address
Quem Hospital, Ahmadabad Ave., Mashhad, Iran
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9137913316
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elyasis@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Faculty of Pharmacy, Ferdowsi University, Vakilabad Boulevard
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17871 91886
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tafaghodim@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Sepideh Elyasi

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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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
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
Yes - There is a plan to make this available

Title and more details about the data/document
The findings will be published in an article. Study protocol and statistical analysis will be used for article publication.

When the data will become available and for how long
One year after the end of the study it will be published and available in databases.

To whom data/document is available
If the funding sponsor allowed, the findings will be available for researchers, clinicians, and scientific centers.

Under which criteria data/document could be used
The other researchers can use our findings in their review articles and meta analysis.

From where data/document is obtainable
For this purpose, you can contact with Sepideh Elyasi, at Clinical Pharmacy Department, School of Pharmacy, Vakil Abad Aven., Mashhad, Iran. Email: elyasis@mums.ac.ir

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