

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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 Qaem 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)

###### Phone

+98 51 3180 1588

###### Email address

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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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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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

**Street address**

Vakilabad Boulevard; Ferdowsi University; Faculty of Pharmacy

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## Person responsible for scientific 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

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate Professor

**Latest degree**

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**Other areas of specialty/work**

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**Province**

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17871 91886

**Phone**

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**Email**

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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**