

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of statin effect on COVID19 duration and complications

Protocol summary

Study aim

Determining the effect of statin use in reducing the length of hospital and complications in corona

Design

Clinical trial with control group, with parallel, non-blind, simple randomized group, phase 2 on 60 patients.

Settings and conduct

-Patients admitted to Shahid Beheshti Hospitals with COVID 19 By receiving oxygen by reserve bag, they have less than 93% oxygen saturation Provided you have an entry criterion, in two groups of 30 people, it was selected as control and intervention. A simple enter the blockade allocation into one of two treatment groups; n addition to receiving treatment protocol from the Ministry of Health, the intervention group will be treated with statin after obtaining informed consent, and the second group will be treated only with the protocol of the Ministry of Health.

Participants/Inclusion and exclusion criteria

inclusion: 1.Age 18 2. No history of statin use in the past 3.O2 saturation above 93% by receivingO2 4. Liver enzymes in the normal range 5. Do not take interfering drugs in concomitant use with statins as defined by the FDA' exclusion: 1. P kidney disease in the ESRD stage, GFR less than 15 2. Cardiogenic shock 3. Allergy to coronavirus protocol drugs 4. Recent acute renal failure-transplanted kidney-Hemodialysis patients 5. CT Angio-MR Angio-Angiography in the last 2 weeks. 6. Receiving nephrotoxic substances during the last two weeks 7. Instability of the patient's hemodynamic status 8. Any type of cancer with previous kidney damage 9. Increase CPK AST (3)

Intervention groups

In addition to receiving treatment protocol from the Ministry of Health, the intervention group under statin treatment after obtaining conscious consent. And the second group is only treated by the protocol of the Ministry of Health

Main outcome variables

Rehospitalization - Mortality - Lung fibrosis - Recovery

During hospitalization filling out checklists

General information

Reason for update

Acronym

استاتین

IRCT registration information

IRCT registration number: **IRCT20201128049508N1**

Registration date: **2020-12-28, 1399/10/08**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-28, 1399/10/08**

Update count: **0**

Registration date

2020-12-28, 1399/10/08

Registrant information

Name

Mohammad Bagherzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3612 2000

Email address

mbagherzadeh@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of statin effect on COVID19 duration and complications

Public title

effect of statin in COVID19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 No history of statin use in the past Oxygen saturation above 93% by receiving oxygen reservation bag Liver enzymes in the normal range Lack of musculoskeletal disease such as myopathy. Known neuropathy Do not take drugs that interfere with the use of statins as defined by the FDA

Exclusion criteria:

People with kidney disease in the ESRD stage, in other words GFR less than 15 Cardiogenic shock Recent acute renal failure-Severe heart-liver failure Patients with transplanted kidney People who have had CT Angio-MR Angio-Angiography in the last 2 weeks. Receiving nephrotoxic substances during the last two weeks Instability of the patient's hemodynamic status History of taking statins Increase CPK (double)AST (triple) SPO2 below 93% despite receiving oxygen reservation bag

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

The sampling method will be simple randomization. First, a completely random list of patients with coronary artery disease is prepared and coded to each of them, and 60 people will be selected as a sample using a random number table

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی قم

Street address

shahid beheshti blv

City

Qom

Province

Ghoum

Postal code

3719964797

Approval date

2020-08-25, 1399/06/04

Ethics committee reference number

IR.MUQ.REC.1399.176

Health conditions studied

1

Description of health condition studied

Covid 19

ICD-10 code

B97.2

ICD-10 code description

Coronavirus as the cause of diseases classified elsewhere

Primary outcomes

1

Description

death

Timepoint

every day

Method of measurement

View

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to receiving treatment protocol from the Ministry of Health, after obtaining informed consent, it will be treated with interferon.

Category

Treatment - Drugs

2

Description

Control group: They are treated only by the protocol of the Ministry of Health

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

shahid beheshti hospital

Full name of responsible person

mohammad bagherzadeh

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

mohammad

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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

Ghoum 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

Ghoum University of Medical Sciences

Full name of responsible person

Mohammad Bagherzadeh

Position

Assistant profssor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

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Position

Assistant profssor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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 Assistant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

All potential data can be shared after people have not been identified

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

It will be available for researchers working in academic and scientific institutions

Under which criteria data/document could be used

According to the rules of the COPE

From where data/document is obtainable

m_bagherzadeh3@yahoo.com

What processes are involved for a request to access data/document

m_bagherzadeh3@yahoo.com

Comments