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 receiving02 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 اخلاقدانشگاه 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

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
shahid beheshti hospital
Full name of responsible person
mohammad bagherzadeh
Street address
shahid beheshti blv
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
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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

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Person responsible for updating data

Contact

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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