Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

Evaluating the effect of Cyclosporine in prognosis and clinical improvement in patients with COVID-19: A Randomized Clinical Trial Study

Protocol summary

Study aim
Determining the effect of cyclosporine on clinical improvement and prognosis of patients with Covid-19

Design
Parallel single-blind randomized clinical trial study

Settings and conduct
Eligible patients hospitalized in Sina Hospital are randomly assigned to one of two groups after receiving informed consent. The objectives of the study, possible beneficial effects and possible side effects for the patients participating in the study or their relatives will be explained. Patients using balanced blocks randomization are divided into two groups including receiving standard treatment of Covid-19 and standard treatment + cyclosporine. Given that patients will be unaware of the type of medication used, therefore, the study will be single blind.

Participants/Inclusion and exclusion criteria
18-60 years patients with PCR positive test, with acute respiratory infectious symptoms and severe lung involvement, will be included in the study and pregnant or lactating women patients or patients with cancer or intubated exclude from the study.

Intervention groups
Intervention group: Receiving routine treatment (according to national protocol) + Cyclosporine and Control group: Receiving routine treatment (according to national protocol)

Main outcome variables
Clinical outcome and prognosis of patients with Covid-19

General information

Reason for update
Removing placcebo

Acronym

IRCT registration information
IRCT registration number: **IRCT20200426047206N3**
Registration date: **2020-07-21, 1399/04/31**
Registration timing: **prospective**

Last update: **2020-07-25, 1399/05/04**
Update count: **1**

Registration date
2020-07-21, 1399/04/31

Registrant information

Name
Salman Khazaei

Name of organization / entity

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Iran (Islamic Republic of)

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+98 81 3838 0548

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-22, 1399/05/01

Expected recruitment end date
2020-11-21, 1399/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effect of Cyclosporine in prognosis and clinical improvement in patients with COVID-19: A Randomized Clinical Trial Study

Public title
The effect of Cyclosporine in prognosis and clinical improvement in patients with COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Positive PCR test Age between 18-60 years patient with acute respiratory infectious symptoms and lung involvement non-intubated patients
Exclusion criteria:
Allergy to Cyclosporin Not willing to participate Patients with cancer Under treatment with immunosuppressor drugs Pregnancy or breastfeeding
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
For this purpose, we will use the BalancedBlock Randomization method (block size=4). Random allocation software will be used for this purpose. At first, we prepare two sheets of paper. We write "Intervention" on a paper and "Standard treatment" on another. Mix the sheets together and place them on the desk drawer. With the referral of each of the eligible patients, one of the cards will be drawn randomly and based on this drawn card, it will be assigned to one of the two groups. It should be noted that the drawn sheets will not be returned to the drawer until all four sheets have been removed. After all four sheets are drawn randomly, all the sheets are returned to the drawer and the above operation will be continued for the next four patients until the desired sample size is reached.
Blinding (investigator's opinion)
Single blinded
Blinding description
We describe two treatment groups for the patients, but allocation to group are random and patients are not aware from allocation
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan University of Medical Sciences
Street address
Fahmideh Street
City
Hamadan
Province
Hamadan
Postal code
6517838778
Approval date
2020-07-11, 1399/04/21
Ethics committee reference number
IR.UMSHA.REC.1399.355

Health conditions studied

1

Description of health condition studied
COVID-19 disease
ICD-10 code
U07.1
ICD-10 code description
COVID-19

Primary outcomes

1

Description
Change oxygenation
Timepoint
Daily for two weeks
Method of measurement
pulse oximeter

2

Description
Creatinine clearance status
Timepoint
Days 2, 4 and 6
Method of measurement
laboratory exam

3

Description
Inflammatory factors
Timepoint
Days 1 and 7
Method of measurement
Flow Cytometry

4

Description
Number of days hospitalized in the ward

Timepoint
Seventh day onward
Method of measurement
day

5

Description
Serum D.dimer
Timepoint
Days 1,3 and 7
Method of measurement
Enzymes

6

Description
Serum ferritin level
Timepoint
Days 1,3 and 7
Method of measurement
laboratory test

7

Description
TCD4+, TCD8+, B Cell
Timepoint
Days 1 and 7
Method of measurement
Flow Cytometry

8

Description
CRP
Timepoint
Days 1 and 7
Method of measurement
mg/L

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients receive low-dose cyclosporine for at least 7 days orally.Also, the routine treatments (The last national protocol for COVID-19 treatment) will be given to patients according to the physician's supervision.
Category
Treatment - Drugs

2

Description
Control group: The routine treatments (The last national protocol for COVID-19 treatment) will be given to these patients according to the physician's supervision.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Dr Fariba Keramat
Street address
Mirzadeh Eshghi Street
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Hamadan
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6516848741
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faribakeramat@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Saeed Bashirian
Street address
Fahmideh Street
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Postal code
6571838678
Phone
+98 81 3838 0717
Email
s_bashirian@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Hamadan 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

Hamedan University of Medical Sciences

Full name of responsible person

Salman Khazaei

Position

Assistance professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

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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