Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study of Methylprednisolone effects on treatment and clinical symptoms and laboratory signs of Iranian COVID-19 patients: a clinical trial study

Protocol summary

Study aim
Evaluation of Methylprednisolone effects on treatment and clinical symptoms and laboratory signs of Iranian COVID-19 patients

Design
This study is a two arm parallel group, single blinded clinical trial in phase 2 which will be carried out on 68 hospitalized COVID-19 patients. Patients randomly divided into two groups.

Settings and conduct
68 hospitalized COVID-19 patients in Shariati and Imam khomeini hospital and Isfahan medical university will be included in this study.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: COVID-19 patient with confirmed by positive PCR test for SARS-CoV-2 or abnormal CT scan finding (bilateral, sub pleural, peripheral ground glass opacities), Blood oxygen saturation <93%, Respiratory Rat >30 breaths/minute, before connecting to ventilator and intubation. Exclusion criteria: Patients with uncontrolled type I diabetes and blood pressure and positive pro-calcitonin or active infection, and taking any immune-suppressor agents.

Intervention groups
Control group: will receive standard regimen for COVID-19. Methylprednisolone group: will receive standard regimen for COVID-19 plus Methylprednisolone (250mg for 3 days).

Main outcome variables
This clinical trial will be carried out on 68 hospitalized COVID-19 patients in Shariati and Imam khomeini hospital of Tehran and Isfahan medical university, Iran. Patients will be received 250mg methylprednisolone pulse for 3 days. In this study, patients don't know which group of them will use the medicine. Physician and clinicians team know about the medicine and intervention groups.

General information

Reason for update
update the blindness, randomization of the study, sample size and the time of clinical record

Acronym

IRCT registration information
IRCT registration number: **IRCT20200404046947N1**
Registration date: **2020-04-15, 1399/01/27**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-22, 1399/03/02**
Update count: **1**

Registration date
2020-04-15, 1399/01/27

Registrant information

Name
Abdolrahman Rostamian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2691 1458

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arostamian@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-28, 1399/01/09

Expected recruitment end date
2020-05-28, 1399/03/08

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of Methylprednisolone effects on treatment and clinical symptoms and laboratory signs of Iranian COVID-19 patients: a clinical trial study

Public title
Effect of Methylprednisolone on treatment of COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
COVID-19 patient confirmed by positive PCR test for SARS-CoV-2 or abnormal CT scan finding (bilateral, sub pleural, peripheral ground glass opacities), Blood oxygen saturation <93%, Respiratory Rate >30 breaths/minute, before connecting to ventilator and intubation.

Exclusion criteria:
Patients with uncontrolled type I diabetes, blood pressure, positive pro-calcitonin, active infection, and taking any immune-suppressor agents, will exclude from the study.

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study patients don't know which group of them will use the medicine. Physician and clinicians team know about the medicine and intervention groups.

Placebo
Not used

Assignment
Parallel

Other design features
This study is double blinded clinical trial in phase 2 which will be carried out on 68 hospitalized COVID-19 patients. Patients randomly divided into two groups. Control group and treatment group which received of medicine (250 mg methylprednisolone pulse for 3 days). Clinical signs of patient including heart rate, blood pressure body temperature, O2 saturation, laboratory tests result (CBC, ESR, CRP, VBG, IL-6, Ferritin, Troponin, D-dimer) will be recorded before and after treatment (after 3 days of treatment and at discharge time). In addition, dyspnea, cough, GI Symptom, myalgia, chest pain and BORG Score will be assessed before and after treatment (after 3 days of treatment and at discharge time). Need an oxygen therapy (nasal Cannula, mask Oxygen, reserve Mask, NIV and invasive ventilation) will also be recorded before and after treatment (after 3 days of treatment and at discharge time).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice-Chancellor in Research Affairs Tehran University of Medical Science

Street address
Central Building of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

City
Tehran

Province
Tehran

Postal code
1416753955

Approval date
2020-03-27, 1399/01/08

Ethics committee reference number
IR.TUMS.VCR.REC.1399.054

Health conditions studied

1

Description of health condition studied
COVID-19 disease

ICD-10 code
U07.2, U07

ICD-10 code description
COVID-19

Primary outcomes

1

Description
Radiographic features Findings

Timepoint
Before and at discharge time only in patients agreed to give informed consent

Method of measurement
CT scan

2

Description
Mortality rate

Timepoint
Before and after

Method of measurement
Observation

3

Description
O2 saturation
Timepoint
Before and after (by 3 days of treatment and at discharge)
Method of measurement
Pulse Oximeter

4

Description
Need an oxygen therapy
Timepoint
Before and after (at day 3 and discharge time)
Method of measurement
clinical

Secondary outcomes

1

Description
laboratory tests
Timepoint
Before and after (at day 3, and discharge time)
Method of measurement
Para-clinical

Intervention groups

1

Description
Intervention group: Patients hospitalized with COVID-19 disease who in addition to their standard treatment will be received 250mg/day Methylprednisolone for 3 days.
Category
Treatment - Drugs

2

Description
Control group: Patients hospitalized with COVID-19 disease who are received standard treatment
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Ahmadreza Jamshidi
Street address
Shariati Hospital, Jalal-e-Al-e-Ahmad Hwy
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2

Recruitment center
Name of recruitment center
Imam khomeini Hospital
Full name of responsible person
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3

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

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Name of organization / entity
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Abdorahman Rostamian
Position
Assistant professor
Latest degree
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

It will be published as an article

When the data will become available and for how long

After printing the article

To whom data/document is available

All medical professionals and scientiscts

Under which criteria data/document could be used

There is no restriction on access to information

From where data/document is obtainable

Dr. Abdorahman Rostamian, Tehran University of Medical Science

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

Refer to the project supervisor

Comments