

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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 Rate >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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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.

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Province

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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

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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

Sponsor**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
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Full name of responsible person
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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 scientists

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