

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

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

Protocol summary

Study aim

Study of Prednisolone effects on treatment, clinical symptoms and laboratory signs of Iranian COVID-19 patients

Design

This study is a two arm parallel group, double blinded clinical trial in phase 2 which will be carried out on 60 hospitalized COVID-19 patients. Patients randomly divided into two groups.

Settings and conduct

60 hospitalized COVID-19 patients in Shariati, Imam Khomeini, Baharloo and Valiasr hospitals will be included in this study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: COVID-19 patient with Acute Respiratory Distress Syndrome (ARDS) and 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%, not responding to standard COVID-19 treatment after 48-72h. Exclusion criteria: Patients with type I diabetes, asthma and lung diseases, malignancies, kidney and heart failure, uncontrolled high blood pressure, positive pro-calcitonin and active infection, patients taking immunosuppressive drugs and corticosteroids, pregnant or lactating women, prescribing antibiotics due to a bacterial infection

Intervention groups

Control group: Will receive standard treatment for COVID-19 disease. Prednisolone group: In addition to standard treatment will received 0.5mg/kg prednisolone in three divided doses up to 30 mg per day for 5-7 days.

Main outcome variables

Radiographic features findings, Mortality rate, O2 saturation, Need for an oxygen therapy and Laboratory tests

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081027001411N3**

Registration date: **2020-06-01, 1399/03/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-01, 1399/03/12**

Update count: **0**

Registration date

2020-06-01, 1399/03/12

Registrant information

Name

Ahmad Reza Jamshidi

Name of organization / entity

Iran Rheumatology Center

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-29, 1399/01/10

Expected recruitment end date

2020-06-30, 1399/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

Effect of Prednisolone on treatment of COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

COVID-19 patient with Acute Respiratory Distress Syndrome (ARDS) and confirmed by positive PCR test for SARS-CoV-2 or confirmed by abnormal CT scan finding (bilateral, sub pleural, peripheral ground glass opacities), With blood oxygen saturation <93%, Not responding to standard COVID-19 treatment after 48-72h

Exclusion criteria:

A history of type I diabetes, asthma and lung diseases, malignancies, kidney and heart failure, uncontrolled high blood pressure, positive pro-calcitonin and active infection Taking immunosuppressive drugs and corticosteroids Pregnant or lactating women Prescribing antibiotics due to a bacterial infection

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Balanced Randomization Method will be used. Patients will allocate to two groups with Block Balanced Randomization Method. The size of each random block is 2, and patients will be allocated equally to the two intervention groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study patients don't know which group of patients will use the medicine. Physician and clinicians team know about the drug and group who use the drug.

Placebo

Not used

Assignment

Parallel

Other design features

This study will be carried out on 60 hospitalized COVID-19 patients. Patients randomly divided into two groups: control group and treatment group which received 0.5mg/kg prednisolone in three divided doses up to 30 mg per day for 5-7 days. Clinical signs of patient including heart rate, blood pressure body temperature, O2 saturation, CT scan findings, laboratory tests result (CBC, ESR, CRP, Ferritin, Troponin, D-dimer) will be

recorded before treatment and at day 8 and day 14). In addition, Patients' mortality rates, length of hospitalization, and the need for mechanical ventilation and intubation are recorded in two groups of intervention and control.

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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Tehran

Province

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Postal code

1416753955

Approval date

2020-03-27, 1399/01/08

Ethics committee reference number

IR.TUMS.VCR.REC.1399.055

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 treatment with Prednisolone and at days 8 and 14 after treatment

Method of measurement

CT scan

2**Description**

Mortality rate

Timepoint

Before and after treatment with Prednisolone

Method of measurement

Observation

3

Description

O2 saturation

Timepoint

Before treatment with Prednisolone and at days 8 and 14 after treatment

Method of measurement

Pulse Oximeter

4

Description

Need for an oxygen therapy

Timepoint

Before treatment with Prednisolone and at days 8 and 14 after treatment

Method of measurement

Clinical

Secondary outcomes

1

Description

CBC laboratory test

Timepoint

Before treatment with Prednisolone and at days 8 and 14 after treatment

Method of measurement

Para-clinical

2

Description

ESR laboratory test

Timepoint

Before treatment with Prednisolone and at days 8 and 14 after treatment

Method of measurement

Para-clinical

3

Description

CRP laboratory test

Timepoint

Before treatment with Prednisolone and at days 8 and 14 after treatment

Method of measurement

Para-clinical

4

Description

Ferritin laboratory test

Timepoint

Before treatment with Prednisolone and at days 8 and 14 after treatment

Method of measurement

Para-clinical

5

Description

D-Dimer laboratory test

Timepoint

Before treatment with Prednisolone and at days 8 and 14 after treatment

Method of measurement

Para-clinical

6

Description

Troponin laboratory test

Timepoint

Before treatment with Prednisolone and at days 8 and 14 after treatment

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 received 0.5mg/kg prednisolone in three divided doses up to 30 mg per day for 5-7 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

Mohammad Abdolahi

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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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mam Khomeini Hospital Complex, Tohid Squire

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3

Recruitment center

Name of recruitment center

Baharloo Hospital

Full name of responsible person

Sasan Falahi

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4

Recruitment center

Name of recruitment center

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Full name of responsible person

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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

Tehran University of Medical Sciences

Full name of responsible person

Ahmadreza Jamshidi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Rheumatology

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Person responsible for scientific inquiries

Contact

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Mahdi Mahmoudi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Person responsible for updating data

Contact

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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

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. Ahmadreza Jamshidi, Tehran University of Medical Science

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

Refer to the project supervisor

Comments