Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 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 stamdard 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
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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 stamdard 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.

City
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
Maryam Edalatifard

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3

Recruitment center

Name of recruitment center
Baharloo Hospital

Full name of responsible person
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4

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
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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Associate professor

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Other areas of specialty/work
Immunology

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Person responsible for updating data

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Name of organization / entity
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Consultant

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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 scientiscts

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