

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Comparing efficacy and safety of different doses of dexamethasone in hospitalized patients with COVID-19

Protocol summary

Study aim

Comparing efficacy and safety of different doses of dexamethasone in hospitalized patients with COVID-19

Design

This is an open-label, randomized clinical trial. Eligible patients will be assigned to one of the groups of the study according to the permuted block randomization.

Study phase is 2-3.

Settings and conduct

After introduction of the study protocol for admitted patients to Imam Khomeini Hospital, Tehran, Iran, and recording consent form, concomitant with the recommended standard of care, eligible patients will be assigned to one of the dexamethasone 4 mg IV BD, 8 mg IV BD or 8 mg IV TDS or more for 7-10-days. During the study period, patients will be monitored for response to the treatment and complications.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hospitalized adult patients with diagnosis of COVID-19. Exclusion criteria: Patients with contraindications of corticosteroids use, pregnancy and location

Intervention groups

Concomitant with the standard of care, patients will be assigned to one of the following groups: 1- Dexamethasone 4 mg IV BD for 7-10-days 2- Dexamethasone 8 mg IV BD for 7-10-days 3- Dexamethasone 8 mg IV TDS or more for 7-10-days Patients will be daily followed for I response to the therapy and adverse reactions.

Main outcome variables

Improvement of patients' chief complain, Improvement of peripheral blood oxygen saturation, Decrease in CRP, Hyperglycemia, Mood changes, Myopathy, Secondary infections

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100228003449N31**

Registration date: **2020-10-08, 1399/07/17**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-08, 1399/07/17**

Update count: **0**

Registration date

2020-10-08, 1399/07/17

Registrant information

Name

Hossein Khalili

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 4715

Email address

khalilih@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-26, 1399/07/05

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing efficacy and safety of different doses of dexamethasone in hospitalized patients with COVID-19

Public title

Corticosteroids in COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Adult patients (18-85 years old) With diagnose of COVID-19 according to laboratory, clinical or radiological findings With indication for hospitalization

Exclusion criteria:

Contraindication of corticosteroids (uncontrolled diabetes mellitus, active bacteria, fungal or parasite infections, hypersensitivity reactions, close angle glaucoma, uncontrolled neuropsychiatric disorders, unstable cardiovascular disorders including acute myocardial infarction, acute thrombosis, uncontrolled hypertension, viral hepatitis, history of corticosteroids induced myopathy) Pregnancy Lactation History of recent corticosteroids or other immunosuppressant drugs use

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **119**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done according to the blocks randomization method. Regarding to the sample size, 3 patients will be include in each block. According to 3 different doses of A-B-C, six different combinations of ABC, ACB, BAC, BCA, CAB, CBA exist. SAS procedure PROC PLAN will be applied to generate the random numbers. For numbers 0-1/6, 1/6-2/6, 2/6-3/6, 3/6-4/6, 4/6- 5/6 and 5/6-6/6 following combinations ABC, ACB, BAC, BCA, CAB, CBA will be assigned respectively.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University Of Medical Sciences

Street address

Ghods Ave. Tehran University of Medical Sciences, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417614411

Approval date

2020-09-09, 1399/06/19

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.430

Health conditions studied**1****Description of health condition studied**

COVID-19 pneumonia

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes**1****Description**

Improvement of patients' chief complaint

Timepoint

Daily

Method of measurement

Clinical examination

2**Description**

Improvement in peripheral blood oxygen saturation

Timepoint

Daily

Method of measurement

Pulse oximetry

3**Description**

Decrease in serum CRP

Timepoint

Every other day

Method of measurement

Laboratory data

4**Description**

Hyperglycemia

Timepoint

Daily

Method of measurement

Glucometer

5

Description

Changes in mood

Timepoint

Daily

Method of measurement

Psychiatric examination

6

Description

Myopathy

Timepoint

Daily

Method of measurement

Physical examination

7

Description

Secondary infections

Timepoint

Daily

Method of measurement

Clinical examination and laboratory parameters (CBC)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Concomitant with the standard of care, patients in group 1 will receive dexamethasone 4 mg IV BD for 7-10-days. Patients will be daily followed for response to the therapy and adverse reactions.

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group: Concomitant with the standard of care, patients in group 2 will receive dexamethasone 8 mg IV BD for 7-10-days. Patients will be daily followed for response to the therapy and adverse reactions.

Category

Treatment - Drugs

3

Description

Intervention group: Concomitant with the standard of care, patients in group 3 will receive dexamethasone 8 mg IV TDS or more for 7-10-days. Patients will be daily followed for response to the therapy and adverse reactions.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Hossein Khalili

Street address

Keshavarz Boulevard

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Tehran

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Postal code

1417614411

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+98 21 6695 4715

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khalilih@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Vice Chancellor for Research, Tehran University of Medical Sciences, Ghods Ave., Tehran, Iran

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02166706141

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msahrai@sina.tums.ac.ir

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

Hossein Khalili

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave., Tehran, Iran

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Results of the study will be published. The study protocol and statistical analysis will be included in the manuscript

When the data will become available and for how long

One year after finishing the study, data will be published and will be available in databases

To whom data/document is available

After permission from the sponsor, data of the study will be available for academic researchers, physicians and scientific institutes

Under which criteria data/document could be used

Other researchers are permitted to include the results in their systematic reviews and metaanalysis

From where data/document is obtainable

For this you may ask Hossein Khalili through following information: Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave., Tehran, Iran Postal code: 1417614411 E-mail: khalilih@tums.ac.ir

What processes are involved for a request to access

data/document

After receiving the query, dependent on the requested data, the scientific responsible person of the study will response to the query in coordinate with the sponsor within 2 weeks

Comments