Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 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 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 l 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)

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+98 21 6695 4715

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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 Boulveard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraian
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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
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Person responsible for updating data

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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 form 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 included 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