Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study of Dexamethasone effects on the improvement of clinical symptoms and laboratory signs of Iranian COVID-19 patients: a clinical trial study

Protocol summary

Study aim

Evaluation of Dexamethasone effects on improvement of Iranian COVID-19 patients

Design

This study is a clinical trial with a control group, with single blind double-sided groups in the second phase. Which will be performed on 200 outpatients with COVID-19 disease. Patients are randomly divided into two groups of intervention and placebo based on the method of Permuted balanced block randomization and according to the patient file number.

Settings and conduct

A total of 200 outpatients with COVID-19 with respiratory symptoms referred to clinics in Imam Khomeini, Amir-Alam, Emam Ali and Ziaian hospitals are enrolled.

Participants/Inclusion and exclusion criteria

Patients with Covid 19 who test positive for SARS-CoV-2 by RT-PCR or diagnosed by CT scan criteria and saturated oxygen between 95-90% are randomly entered into the study. Exclusion criteria: Having a history of underlying diseases such as diabetes, malignancies, renal and heart failure, uncontrolled hypertension, other active infections, use of immunosuppressive drugs and corticosteroids, pregnant women or breastfeeding

Intervention groups

Control group: will receive standard regimen for COVID-19. Dexamethasone group: will receive standard regimen for COVID-19 plus 8 mg Dexamethasone (If the patient's condition does not change, the dose will repeat after 48 hours).

Main outcome variables

Clinical symptoms including: mortality rate, blood oxygen saturation level, need for oxygen therapy and laboratory tests before and one and two weeks after treatment will be evaluated and recorded in a questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201015049030N1**
Registration date: **2020-11-07, 1399/08/17**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-07, 1399/08/17**
Update count: **0**

Registration date

2020-11-07, 1399/08/17

Registrant information

Name

Mohammadreza Salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

mr-salehi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-11, 1399/06/21

Expected recruitment end date

2020-12-10, 1399/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Study of Dexamethasone effects on the improvement of clinical symptoms and laboratory signs of Iranian COVID-19 patients: a clinical trial study

Public title
Effect of Dexamethasone on treatment of COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Outpatients with Covid 19 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 between 90-95% Patients with severe respiratory symptoms such as cough, shortness of breath and severe shortness of breath or CRP above 20 or after three days of standard treatment worsened symptoms of the disease, including exacerbated fevers, aggravated weakness or aggravated shortness of breath based on the physician's clinical judgment

Exclusion criteria:
Patients with a history of underlying disease such as diabetes, malignancies, renal and heart failure, uncontrolled hypertension, and taking immunosuppressive drugs and corticosteroids Patients with other active infections Pregnant or lactating women

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Assignment of patients to the intervention and control groups will be done based on the Permuted balanced block randomization method and according to the patients' file numbers.

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

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
Tehran

Postal code
1416753955

Approval date
2020-09-10, 1399/06/20

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.432

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
O2 saturation

Timepoint
Before, one and two weeks after dexamethasone treatment

Method of measurement
Pulse Oximeter

2

Description
Mortality rate

Timepoint
Before and after dexamethasone treatment

Method of measurement
Observation

3

Description
Need for an oxygen therapy

Timepoint
Before and after dexamethasone treatment

Method of measurement
Clinical

4

Description
Constitutional
Timepoint
Before, one and two weeks after dexamethasone treatment
Method of measurement
Clinical

5

Description
Needs of hospitalization
Timepoint
Before and after treatment
Method of measurement
Observation

Secondary outcomes

1

Description
CRP laboratory test
Timepoint
Before, one and two weeks after dexamethasone treatment
Method of measurement
Para-clinical

2

Description
CBC laboratory test
Timepoint
Before, one and two weeks after dexamethasone treatment
Method of measurement
Para-clinical

Intervention groups

1

Description
Intervention group: 100 outpatients with Covid 19 with respiratory symptoms who in addition to their standard treatment will receive 8mg Dexamethasone (If patient's condition does not change, the dose will repeat after 48 hours).
Category
Treatment - Drugs

2

Description
Control group: 100 outpatients with Covid 19 with respiratory symptoms who are received standard treatment
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini Hospital
Full name of responsible person
Mohamadreza Salehi
Street address
Imam Khomeini Hospital Complex, Tohid Squre
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2

Recruitment center
Name of recruitment center
Ziaeian
Full name of responsible person
Saeed Reza Jamali Moghadm
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3

Recruitment center
Name of recruitment center
Amir-Alam Hospital
Full name of responsible person
Ali Asadolahi Amin
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4

Recruitment center

Name of recruitment center
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Full name of responsible person
Mojtaba Hedayat Yaghoobi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Mohammad Ali Sahraian

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

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
Mohamadreza Salehi

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Infectious diseases

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Person responsible for scientific inquiries

Contact

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Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Immunology

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Others
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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
t 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. Mohamad Reza Salehi, Tehran University of Medical Science
What processes are involved for a request to access data/document
Refer to the project supervisor
Comments