

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evolution of the efficacy and safety of Dexamethasone administration in patients with mild to moderate COVID-19 acute respiratory disease syndrome

Protocol summary

Study aim

Studying the therapeutic effect and side effects of dexamethasone in COVID-19 positive patients with mild to moderate symptoms

Design

Clinical trial with parallel randomized groups

Settings and conduct

This is a randomized clinical trial which will be done at Dr. Masih Daneshvari Hospital

Participants/Inclusion and exclusion criteria

In this study, 18 year old patients with confirmed COVID-19 through RT-PCR, who signed consent form, were included in the study. Furthermore, patients with PiO_2/FiO_2 between 100 and 300 mmHg, and bilateral lung infiltration with mild to moderate symptoms were included. Patients with acute and chronic renal disease, liver disease, hyperglycemia, with sever symptoms were excluded from this study.

Intervention groups

Patients in treatment group received dexamethasone (manufactured by Abouraihan Pharmaceutical Company) 20 mg intravenously from day one to 5 then 10 mg for days 6 to 10. patients in control group did not receive dexamethasone. patients in both groups received oxygen, fluid support, and lopinavir/ritonavir 200/50 mg to Tab BID as standard therapy.

Main outcome variables

Need of mechanical ventilation and death

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151227025726N17**

Registration date: **2020-05-31, 1399/03/11**

Registration timing: **retrospective**

Last update: **2020-05-31, 1399/03/11**

Update count: **0**

Registration date

2020-05-31, 1399/03/11

Registrant information

Name

Farzaneh Dastan

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 912 270 5933

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-24, 1399/02/05

Expected recruitment end date

2020-05-25, 1399/03/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evolution of the efficacy and safety of Dexamethasone administration in patients with mild to moderate COVID-19 acute respiratory disease syndrome

Public title

Evolution of the efficacy and safety of Dexamethasone administration in COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients between 18 and 65 years old Laboratory COVID-19 confirmed with RT-PCR Mild to moderately ill patients Patients with PaO₂/FiO₂ between 100-300 Signed the consent form

Exclusion criteria:

Acute or chronic renal impairment (Creatinin rise more than 3 units in the last 48 hours and/or GFR less than 30 mL/min) Chronic liver disease (Rise in LFTs more than 5 times and/or 3 times rise in LFTs in symptomatic patients and/or Child pugh C,D) Allergy to corticosteroids while being injected with extravasation and signs of anaphylactic shock. Patients with hyperglycemia Pregnancy and lactation

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method was used in this study. 12 blocks including 4 patients generated with online website (www.sealedenvelope.com). In each block, two patients will be assigned to Dexamethasone group and two patients will be assigned to control group.

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

Vice-Chancellor in Research Affairs - Shahid Beheshti University of Medical Sciences

Street address

3 rd floor, School of Medicine, Evin St, Shahid Chamran Highway

City

Tehran

Province

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Postal code

1983963113

Approval date

2020-04-22, 1399/02/03

Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.071

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

Need for invasive mechanical ventilation

Timepoint

Daily

Method of measurement

Medical record

2

Description

Death

Timepoint

At the end of the study

Method of measurement

Medical record

Secondary outcomes

1

Description

Weaning from oxygen support

Timepoint

Daily

Method of measurement

Medical record

2

Description

Length of hospital stay

Timepoint

At the end of the study

Method of measurement

Medical record

3

Description

Lung radiology changes

Timepoint

At admission time and seven and 14 days later

Method of measurement

At admission time and seven and 14 days later

Intervention groups

1

Description

Intervention group: Patients in dexamethasone group receive intravenous dexamethasone (manufactured by Abouraihan Pharmaceutical Company) at dose of 20 mg/day for day's one to five and then 10 mg/day for day's 6 to 10. Also patients receive supportive treatments including oxygen therapy and fluid therapy. According to the national guideline, patients receive Lopinavir/ritonavir tablets (Hetered Pharmaceutical Company, India) at dose of 200/50 mg in two tablets per day.

Category

Treatment - Drugs

2

Description

Control group: Patients receive supportive treatments including oxygen therapy and fluid therapy. Also, according to the national guideline, patients receive Lopinavir/ritonavir tablets (Hetered Pharmaceutical Company, India) at dose of 200/50 mg in two tablets per day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Payam Tabarsi

Street address

Daraabad, Shahid Bahonar St. (Niavaran), Masih Daneshvari Hospital

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payamtabarsi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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3rd floor, School of Medicine, Evin St, Shahid Chamran Highway

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Mohammadreza Hashemian

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Others

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Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran

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19569-44413

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iran.criticalcare@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Farzaneh Dastan

Position

Assistant Professor, Clinical Pharmacy Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Mirshafiei Langari

Position

Hospital pharmacist

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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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

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

Clinical Study Report

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

Analytic Code

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

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

All potential data can be shared after blinding

When the data will become available and for how long

Six months after publishing

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For research purposes and meta-analysis studies

From where data/document is obtainable

Researchers can meet Dr. farzaneh Dastan at Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran or request data via email: fzh.dastan@gmail.com

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

Official letter to the researchers

Comments