Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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 Hopital

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 PiO2/FiO2 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

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Iran (Islamic Republic of)

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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 corticosteriods 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
Tehran
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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Afshin Zarghi

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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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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Farzaneh Dastan

Position
Assisstant 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

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Hospital pharmacist

Latest degree
Medical doctor

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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 mounts 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