

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison between intravenous dexamethasone and methylprednisolone in treatment of hospitalized patient with COVID-19

Protocol summary

Study aim

Ascertainment and comparison intravenous Dexamethason and Methylprednisolone in treatment of hospitalized patient with COVID-19

Design

This study is a two arm parallel group, single blinded clinical trial, randomized, phase 2-3 which will be carried out on 140 hospitalized COVID-19 patients.

Settings and conduct

140 hospitalized COVID-19 patients in Shahr-e-Kord Hajar hospital included in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: COVID-19 patient under 80 y/o age with confirmed by positive RT-PCR test and bilateral parenchyma infiltration of lung in CT scan, Blood oxygen saturation <93%, who do not take any medication or hospitalization for COVID-19 and do not take any corticosteroid. Exclusion criteria: Patients who leave hospital before discharge or expire in first 24 hour of admission or myocardial infarction during hospitalization. patient with underlying disease who have contraindication of taking corticosteroid such as acute hepatitis or fungal infection and any time patient disagree to continue the study.

Intervention groups

One group will receive Methylprednisolone another group Dexamethason

Main outcome variables

Mortality after 28 days; length of hospital stay; duration of oxygen dependence; mean number of leukocytes and lymphocytes at discharge; transfer to ICU; hypokalemia; impaired fasting blood sugar; mean percentage of oxygen saturation at time of admission; duration apart from the onset of symptoms at the time of admission.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210223050466N1**

Registration date: **2021-03-27, 1400/01/07**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-27, 1400/01/07**

Update count: **0**

Registration date

2021-03-27, 1400/01/07

Registrant information

Name

marziyeh dehghani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3352 2940

Email address

marziehds@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-05-21, 1400/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between intravenous dexamethasone and methylprednisolone in treatment of hospitalized patient with COVID-19

Public title

Comparison between dexamethasone and methylprednisolone in treatment of COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient with COVID-19 Under 80 y/o age With positive RT-PCR test With bilateral lung parenchyma infiltration Blood oxygen saturation <93% Did not take any medication or hospitalization for COVID-19 Taking any Corticosteroid They have tendency to participate in this study

Exclusion criteria:

Patient leave hospital before discharge Patient who expire in first 24 hour after admission Patient with myocardial infarction during hospitalization Patient with underlying disease who have contraindication of corticosteroid such as acute hepatitis, fungal infection All patient who disagree to continue the study

Age

From **15 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization of permutation blocks will be the volume of each block 6 and the randomization list will be prepared using random allocation software and will be provided to a person who has no information about the content of the groups.

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

Ethics committe of Shahr-e-Kord University of Medical Sciences

Street address

Shahr-e-Kord University of Medical Sciences, Kashani Blvd.

City

Shar-e-kord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2020-12-23, 1399/10/03

Ethics committee reference number

IR.SKUMS.REC.1399.228

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**

Blood oxygen saturation

Timepoint

In admission

Method of measurement

pulse oxymeter

2**Description**

Duration of hospitalization

Timepoint

From admission to discharge

Method of measurement

Obsevation

3**Description**

Duration between onset of symptom to start of corticosteroid

Timepoint

Before admission to start of drug

Method of measurement

Patient history

Secondary outcomes

1

Description

Mortality rate after 28 day

Timepoint

From admission to 28 day later

Method of measurement

Observation

2

Description

Number of oxygen dependency days

Timepoint

From admission to oxygen dependency time

Method of measurement

Observation

3

Description

Number of patient who need ICU admission

Timepoint

During hospitalization

Method of measurement

Obsevation

4

Description

Lab data

Timepoint

During admission , hospitalization and discharge

Method of measurement

Laboratory

Intervention groups

1

Description

Intervention group 1: hospitalized patients with COVID-19 who take 60 mg intravenous Methylprednisolone in two divided dose, maximum 10 days in addition to standard treatment.

Category

Treatment - Drugs

2

Description

Intervention group 2: hospitalized patients with COVID-19 who take 8 mg intravenous Dexamethason daily maximum 10 days in addition to standard treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahr-e-Kord Hajar hospital

Full name of responsible person

Zahra Habibi dastenaiei

Street address

Parastar Ave.

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Zahra Habibi dastenaiei

Street address

Vice-Chancellor's Office for Research , Shahr-e-Kord University of Medical Sciences, Kashani Ave.

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habibi.z@skums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Marziyeh dehghani

Position

Internal medicine resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Internal medicine group office, Hajar hospital,
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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Zahra Habibi dastenaee

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Marziyeh Dehghani

Position

Internal medicine resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable