Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 38 3352 2940

Email address
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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 dastenaei
Street address
Parastar Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
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Vice-Chancellor's Office for Research , Shahr-e-Kord University of Medical Sciences, Kashani Ave.
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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
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

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Internal medicine group office, Hajar hospital, Parastar Ave.

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Subspecialist

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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