Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 2021

Evaluation of Methylprednisolone Administration as a Therapeutic Option in the Coronavirus disease 2019 (COVID-19): A Randomized Controlled Study

Protocol summary

Study aim

The effect of methylprednisolone administration vs. dexamethasone on clinical status of COVID-19 patients based on a 9-points WHO ordinal scale

Design

Clinical trial with control group, with parallel groups, triple-blinded, phase 2-3 on 86 patients. Block Randomization was used for randomization.

Settings and conduct

This study was performed in Shahid Faghihi Hospital. This clinical trial was performed on 86 patients with COVID-19 in two intervention and control groups. Patients are treated according to the defined protocol and in addition to that, the intervention group received methylprednisolone and the control group received dexamethasone. Packaging containers contain the drug anonymously, so that none of the patients, assesors, and those performing statistical analysis of the study data will be aware of the patient's treatment group.

Participants/Inclusion and exclusion criteria

Hospitalized patients with confirmed COVID-19 will be included in this study if they fulfilled two primary criteria: Hospitalized patients with positive RT-PCR and age >18 years and O2 saturation of less than 92 in room air. Patients will be excluded if they have a known contraindication to treatment with the steroids, pregnant patients, Uncontrolled DM, Uncontrolled hypertension, Immunodeficiency disorders

Intervention groups

In addition to the standard care recommended by the National Committee, an initial dose of 2mg/kg will be started for all patients in the case group. The patients will receive the mentioned dose for 5 days, which will then be halved every 5 days. Patients in control group, in addition to the standard care , receive dexamethasone 6 mg daily intravenously.

Main outcome variables

Primary endpoint: The all-cause mortality in 28 days and Clinical status Secondary endpoint: Intubation and need for ventilation, admission to ICU, and also duration of hospitalization

General information

Reason for update

Corrections were made regarding randomization and the method of conducting the trial.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200204046369N1**
Registration date: **2020-04-08, 1399/01/20**
Registration timing: **prospective**

Last update: **2020-12-07, 1399/09/17**
Update count: **1**

Registration date

2020-04-08, 1399/01/20

Registrant information

Name
Keivan Ranjbar
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 3627 5344
Email address
keivan.rjr94@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-07, 1399/05/17

Expected recruitment end date

2020-11-15, 1399/08/25

Actual recruitment start date

2020-08-10, 1399/05/20

Actual recruitment end date

2020-11-15, 1399/08/25

Trial completion date

2020-11-15, 1399/08/25

Scientific title

Evaluation of Methylprednisolone Administration as a Therapeutic Option in the Coronavirus disease 2019 (COVID-19): A Randomized Controlled Study

Public title

Effect of Methylprednisolone in treatment of COVID-19 patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

RT-PCR documented SARS-CoV-2 carriage in a nasopharyngeal and oropharyngeal sample at admission Age over 18 years old O2 saturation of less than 92 in room air Hospitalized patients

Exclusion criteria:

A known contraindication to treatment with the steroid Breastfeeding and pregnant patients Uncontrolled diabetes mellitus Uncontrolled hypertension patients who had previously been treated with steroids for any reason O2 Saturation of above 92 in room air Dissatisfaction with the study enrollment Immunodeficiency disorders

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **82**

Actual sample size reached: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation using the block randomization method was performed in all four branches of the strata, based on two prognostic factors such as age (< 55 and ≥55) and disease severity based on O2 Saturation (<85 and ≥85). During random allocation, allocation concealment was noticed. The patient, assessor, and analyzer in the two groups did not have access to the randomization list and type of administered drug (Triple blind)

Blinding (investigator's opinion)

Triple blinded

Blinding description

Packaging containers contain unnamed medicine and there is only one registration number on them in the research center and this number is also available to the treating physicians. Thus, none of the patients, colleagues who are in charge of clinical follow-up and outcome assessment, and those who perform statistical analysis of study data, before the allocation concealment and after the study (blinding), will not know the patient's group therapy.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

zand street

City

Shiraz

Province

Fars

Postal code

7194815644

Approval date

2020-04-04, 1399/01/16

Ethics committee reference number

IR.SUMS.REC.1399.014

Health conditions studied

1

Description of health condition studied

the 2019 novel Corona virus (COVID-19)

ICD-10 code

U07.1

ICD-10 code description

COVID-19 confirmed by laboratory testing.

Primary outcomes

1

Description

The all-cause mortality in 28 days

Timepoint

28 days

Method of measurement

Clinical follow-up

2

Description
Clinical status
Timepoint
5 and 10 days after intervention
Method of measurement
9-points WHO ordinal scale

Secondary outcomes

1

Description
Intubation and need for ventilation, and also admission to ICU
Timepoint
5 and 10 days after intervention
Method of measurement
Clinical follow-up

2

Description
Duration of hospital admission
Timepoint
5 and 10 days after intervention
Method of measurement
Clinical follow-up

Intervention groups

1

Description
Intervention group: In addition to the standard care recommended by the National Committee, an initial dose of 2mg/kg will be started for all patients in the case group. The patients will receive the mentioned dose for 5 days, which will then be halved every 5 days.
Category
Treatment - Drugs

2

Description
Control group: Patients, in addition to the standard care recommended by the National Committee, receive dexamethasone 6 mg daily intravenously.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Faghihi Hospital
Full name of responsible person
Mohsen Moghadami
Street address
Zand street
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7134846316
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moghadami@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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Street address
Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Mohsen Moghadami
Position
Associate professor

Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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moghadami@sums.ac.ir

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
The study results will be published as an article. The study protocol and statistical analysis used in the article will be considered.
When the data will become available and for how long
It will be published a year after the study is completed and will be available in the sources.
To whom data/document is available
Information will be made available after permission of the sponsor for academic researchers, physicians, and academic institutions .
Under which criteria data/document could be used
Other researchers can use the results of the study in their review and meta-analysis.
From where data/document is obtainable
Dr Moghadami, Department of Internal Medicine, Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran
What processes are involved for a request to access data/document
upon request, the corresponding author will respond after consulting with the sponsor of the study.
Comments