Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

evaluation of efficacy and safety of low dose Corticosteroid with severe Pneumonia covid-19

Protocol summary

Study aim
Evaluation of the effect of corticosteroid use in improving patients with COVID-19

Design
Clinical trials have two intervention and control groups, with parallel, one-way, blind, randomized, phase 3 groups on 60 patients. The randomization table was used for randomization.

Settings and conduct
Both groups received resuscitation 6 weeks after discharge (MMRC) requiring re-hospitalization in the past 6 weeks, as well as The rate of improvement of the CT scan is compared to the initial CT scan, which is both read and scored by a radiologist. Be. Thus, in this study, short-term outcome during hospitalization and long-term outcome after 6 weeks in patients who We will review the lowdose corticosteroids.

Participants/Inclusion and exclusion criteria
Covid-19 patients over 18 years of age, definitive case based on RT-PCR +, at least 7 days have passed since the onset of symptoms, at least 5 days of antiviral treatment, O2SAT <93

Intervention groups
In patients admitted to the study with severe hypoxia due to severe pneumonia due to COVID-19 and inclusion criteria, information including vital signs, level of dyspnea (based on Visual Analogue Scale), Sao2 oxygen requirement, demographic characteristics, tests including , CBC, CRP, PCT Imaging The patient including CXR or CT scan is collected through a checklist, then patients are randomly divided into two groups. In both groups, conventional and standard treatments are performed in the same way. The experimental group was treated with methylprednisolone succinate 1-1.75 mg / kg per day and after 5 days, according to the criteria in the questionnaire, the outcome of the disease was evaluated and it was decided whether to continue treatment or discontinue it. The control group did not receive corticosteroids and only received routine treatment.

Main outcome variables
Radiological changes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200611047727N3**
Registration date: **2021-01-03, 1399/10/14**
Registration timing: **retrospective**

Last update: **2021-01-03, 1399/10/14**
Update count: **0**

Registration date
2021-01-03, 1399/10/14

Registrant information

Name
Maryam Sadat Mirenayat

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-22, 1399/05/01

Expected recruitment end date
2020-10-22, 1399/08/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

evaluation of efficacy and safety of low dose Corticosteroid with severe Pneumonia covid-19

Public title

Corton's effect in improving patients with covid-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Corton's effect in improving patients with covid-19 Definitive diagnosis based on Covid-19 test result At least 7 days have passed since the onset of symptoms and at least 5 days of antiviral treatment Oxygen saturation level less than 93

Exclusion criteria:

Patients who are unable to go for follow-up scans

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization: simple Unit of randomization : individual Tools used in randomization : table of random numbers Included patients, in a simple randomized evaluation using even and odd numbers, would got codes for each treatment group. In case of odd numbers, the patient would be enrolled in the group one to receive high flow oxygenation at the first stage and following a washout period, take noninvasive ventilation. On the other hand, patients gotten even numbers would receive noninvasive ventilation for the first stage. Then, after a washout period, high oxygen therapy would be prescribed.

Blinding (investigator's opinion)

Single blinded

Blinding description

The examining physician will not know the type of intervention. Therefore, the study will be performed blindly.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahidbeheshti University of Medical Sciences

Street address

Masih Daneshvari Hospital, Darabad, Shahid Bahonar Ave, Tehran, Iran

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Postal code

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Approval date

2020-04-22, 1399/02/03

Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.074

Health conditions studied

1

Description of health condition studied

covid _19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Radiological changes

Timepoint

Before the intervention and six weeks later

Method of measurement

Through CT scan of the lungs

Secondary outcomes

1

Description

Oxygen levels

Timepoint

Before the intervention and six weeks later

Method of measurement

pulse oximeter

2

Description

Dyspnea

Timepoint

Before the intervention and six weeks later

Method of measurement
In this questionnaire, it is estimated based on MMRC

3

Description
Disease severity
Timepoint
Before the intervention and six weeks later
Method of measurement
Based on the amount of oxygen and clinical symptoms and CT involvement

Intervention groups

1

Description
Intervention group: In the intervention group, methylprednisolone succinate was treated with 0.75-1 mg / kg and after 5 days, due to the information in the questionnaire, the disease outcome was evaluated and if treatment is continued or discontinued, it is requested. .
Category
Treatment - Drugs

2

Description
Control group: The control group receives all common and standard treatments according to the physician, but does not receive corticosteroids. All indicators and evaluation criteria in this group are measured before and after treatment.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital, Darabad, Bahonar Ave, Tehran Town, Iran
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Sponsors / Funding sources

1

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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
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Clinical trial data will be published as an article

When the data will become available and for how long
Start access 6 months after printing results

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Related scientific research

From where data/document is obtainable
مرکز تحقیقات بیماری های مزمن تنفسی بیمارستان مسیح دانشوری تهران

What processes are involved for a request to access data/document
Provide the initial file of the approved research plan

Comments