

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 21 2610 5050

Email address

mirenayat@sbmu.ac.ir

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 get
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

City

Tehran

Province

Tehran

Postal code

1956944413

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

Full name of responsible person

Maryam Mirenayat

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Masih Daneshvari Hospital, Darabad, Bahonar Ave, Tehran Town, 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

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

Maryam Mirenayat

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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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

Atefeh Fakharian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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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