

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Dec 2023

Investigating the efficacy of high dose of glucocorticoid in patients with moderate to severe pneumonia related to COVID-19

Protocol summary

Study aim

Investigating the efficacy of high dose of glucocorticoids in patients with moderate to severe pneumonia related to COVID-19

Design

This study is a single-center, prospective, randomized, open-labeled, controlled, parallel phase 3 clinical trial.

Settings and conduct

Patients who is admitted to Baqiyatallah hospital and is meet the inclusion criteria, is entered to the study are randomly assigned into two groups of intervention and control.

Participants/Inclusion and exclusion criteria

Inclusion criteria: confirmed diagnosis of COVID-19; the written consciously and freely consent to participate in the study; moderate to severe Corona-Virus associated pneumonia; In the first 48 hours of hospitalization, the patient did not show an improving trend; in the first 48 hours after his/her inclusion, there is no possibility of discharge from hospital; Exclusion criteria: history of hypersensitivity reaction to glucocorticoids; recent hospitalization due to COVID-19; receive antivirals before inclusion; receiving Methylprednisolone pulse before inclusion; uncontrolled severe chronic illnesses, including HF, CKD, liver failure, active cancer, DM; receiving immunosuppressing/modulating agents; pregnancy; lactation.

Intervention groups

Intervention group: at Day 1: Amp. Methylprednisolone 500 mg IV infusion over 1 hour. At Day 2 and 3, Amp. Methylprednisolone 250 mg IV infusion over 1 hour. At Day 4 and 5, Amp. Methylprednisolone 100 mg IV infusion over 1 hour. Then, Tab. Prednisolone 25 mg, per oral, daily, until the day of discharge, then Tab. Prednisolone will gradually taper off over during 1 month. Control group: Includes patients who will not receive high-dose of glucocorticoids during hospitalization. All patients in both groups receive routine treatment according to the latest national guideline.

Main outcome variables

Need to receive ICU service

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001165N52**

Registration date: **2020-05-05, 1399/02/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-05, 1399/02/16**

Update count: **0**

Registration date

2020-05-05, 1399/02/16

Registrant information

Name

Yunes Panahi

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8821 1524

Email address

yunespanahi@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the efficacy of high dose of glucocorticoid in patients with moderate to severe pneumonia related to COVID-19

Public title
Investigating the efficacy of high dose of glucocorticoid in patients with moderate to severe pneumonia related to COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed diagnosis of COVID-19, with either lung CT-Scan result, which is typical for COVID-19 pulmonary involvement, or RT-PCR confirmation. The patient has written consciously and freely consent to participate in the study; The patient has moderate to severe Corona-Virus associated pneumonia; In the first 48 hours of hospitalization, the patient did not show an improving trend; In the first 48 hours after his/her inclusion into this study, there is no possibility of discharge from the patient's hospital;
Exclusion criteria:
History of hypersensitivity reaction to glucocorticoids; Recent hospitalization and treatment history due to COVID-19; Receive antiviral drugs before including into this study, such as: Hydroxychloroquine, Kaletra, Ribavirin, Oseltamivir; Receiving Methylprednisolone pulse before including into this study; Uncontrolled severe chronic illnesses, including heart failure, kidney failure, liver failure, active cancer (history of chemotherapy within recent month), diabetes; Receiving immunosuppressing /immunomodulating agents, such as systemic glucocorticoids. Pregnancy; Lactation.

Age
From **18 years** old to **85 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Randomization method is used to randomized the patients. In this method, the number of people assigned to each group is usually almost equal. Blocks are formed based on the considered variables and within each block, half of the people are involved and half are considered as witnesses. The main goal in this method is to balance the number of participants in each group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiyatallah University of Medical Science

Street address

Baqiyatallah University of Medical Science, south Sheikh-Bahaei St., Mollasadra St., Vanak Sq., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2020-04-19, 1399/01/31

Ethics committee reference number

IR.BMSU.REC.1399.099

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

Covid-19

Primary outcomes

1

Description

Need to receive ICU service (occurrence of shock, resistant hypoxemia despite receiving oxygen via reservoir oxygen mask, GCS score drops below 12)

Timepoint

The patient is monitored every 6 hours, but the results are recorded daily in the checklist.

Method of measurement

Physical assessment

Secondary outcomes

1

Description

Mortality rate

Timepoint

30 days after including the study

Method of measurement

Physical assessment

2

Description

Length of hospitalization

Timepoint

The first day and the end of hospitalization

Method of measurement

The hospital record review

3

Description

Radiologic response

Timepoint

At the admission, before the discharge

Method of measurement

CT-SCAN

4

Description

Laboratory changes

Timepoint

Daily

Method of measurement

Blood sample, laboratory analysis

5

Description

Fever

Timepoint

Daily

Method of measurement

Thermometer

6

Description

Respiratory distress

Timepoint

Daily

Method of measurement

Clinical assessment

7

Description

Oxygen saturation without receiving oxygen supplement

Timepoint

It will be measured every 6 hours, but will be recorded daily.

Method of measurement

Pulse-oxymetry device

8

Description

The amount of oxygen received

Timepoint

It will be measured every 6 hours, but will be recorded daily.

Method of measurement

The volume of oxygen consumed through the oxygen mask /Ventilation Volume via Mechanical Ventilation Machine or BiPAP

9

Description

Discharge without the need of ICU service

Timepoint

At discharge time

Method of measurement

Physical assessment

10

Description

Pulmonary function changes

Timepoint

6 week later after discharge

Method of measurement

Spirometry

11

Description

Rate of readmission

Timepoint

until 2 months after discharge

Method of measurement

The hospital record review

12

Description

Side effects

Timepoint

Daily during hospitalization, weekly after discharge

Method of measurement

During hospitalization by clinical evaluation, after discharge by telephone follow-up

Intervention groups

1

Description

Intervention group: At Day 1: Amp. Methylprednisolone 500mg IV infusion over 1 hour. At Day 2 and 3, Amp. Methylprednisolone 250mg IV infusion over 1 hour. At Day 4 and 5, Amp. Methylprednisolone 100mg IV infusion over 1 hour. Then, Tab. Prednisolone 25mg, per oral, daily, until the day of discharge, then Tab. Prednisolone will gradually taper off over during 1 month. All patients will receive routine treatment according to the latest national guideline.

Category

Treatment - Drugs

2**Description**

Control group: Includes patients who will not receive high-dose of glucocorticoids during hospitalization. All patients will receive routine treatment according to the latest national guideline.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Baqiyatallah hospital

Full name of responsible person

Behzad Einollahi

Street address

Baqiyatallah hospital, Mollasadra St., Vanak Sq.,
Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8245 5393

Email

behzad.einollahi@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Gholamhosein Alishiri

Street address

Baqiyatallah University of Medical Science, south
Sheikh-Bahaei St., Mollasadra St., Vanak Sq., Tehran,
Iran.

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8245 5393

Email

R.bmsu@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor****organization/entity?**

Yes

Title of funding source

Bagheiat-allah 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**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Ahmad Zarei

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Baqiyatallah University of Medical Science, south
Sheikh-Bahaei St., Mollasadra St., Vanak Sq., Tehran,
Iran.

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8245 5393

Email

ahmadzareei1373@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Yunes Panahi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Critical Care Pharmacotherapy

Street address

Baqiyatallah University of Medical Science, south
Sheikh-Bahaei St., Mollasadra St., Vanak Sq., Tehran,
Iran.

City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8245 5393
Email
Yunespanahi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Parisa Kianpour
Position
Assistant
Latest degree
Specialist
Other areas of specialty/work
Pharmacotherapy
Street address
Pharmacy faculty, Tehran University of Medical
Science, 16-Azar St., Enghelab Sq., Tehran, Iran.
City
Tehran
Province

Tehran
Postal code
1417614411
Phone
+98 21 6695 4709
Email
parisa_kianpour@yahoo.com

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

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