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-oxymetery 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. Methylprednisolone100mg 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
ahmadzarei1373@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