Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Evaluating the efficacy and safety of intravenous immunoglobulin (IVIG) in COVID-19 patients

Protocol summary

Study aim
Determination of the efficacy and safety of IVIG in treatment of patients with COVID-19
Design
Prospective clinical trial with parallel randomized groups
Settings and conduct
Place of study: Masih Daneshvari Hospital. How to do the study: 80 patients with COVID-19 will be randomly divided in to intervention and control group.
Participants/Inclusion and exclusion criteria
Patients who are diagnosed with COVID-19 by RT-PCR test, who are severely ill, and are between 18 to 65 years old. Patients with oxygen saturation <90% (at rest with nasal cannula 3-4 L/min and FIO2<30-40 L/min) with bilateral pulmonary infiltration were included in the study. Furthermore, patients with allergic reaction while injecting IVIG with severe extravasation and anaphylactic shock, and mildly ill patients were excluded from the study.
Intervention groups
Patients in treatment group will receive hydroxychloroquine 200 mg (Tehran Daroo) twice daily + Lopinavir/Ritonavir 200-50 mg (Hetero Labs Limited) 2 Tab twice daily for 7 days + IVIG (Biotest) 400 mg/Kg for 3 doses. patients in control group will only receive hydroxychloroquine 200 mg (Tehran Daroo) twice daily + Lopinavir/Ritonavir 200-50 mg (Hetero Labs Limited) 2 Tab twice daily for 7 days.
Main outcome variables
Need for mechanical ventilation, need of admission to critical care unit, and death.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20151227025726N20**
Registration date: **2020-07-26, 1399/05/05**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-26, 1399/05/05**
Update count: **0**
Registration date
2020-07-26, 1399/05/05

Registrant information
Name
Farzaneh Dastan
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-07-09, 1399/04/19
Expected recruitment end date
2020-08-09, 1399/05/19
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the efficacy and safety of intravenous immunoglobulin (IVIG) in COVID-19 patients

Public title
Evaluating the effects of intravenous immunoglobulin (IVIG) in COVID-19 patients

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients between 18 and 65 years old. Laboratory confirmed COVID-19 (Corona Virus Disease-19) with RT-PCR (Real-Time Polymerase Chain Reaction). Severely ill patients. Bilateral pulmonary infiltration. SPO2 (Peripheral Capillary Oxygen Saturation) less than 90% (at rest with nasal cannula 3-4 L/min and FIO2 less than 30-40 L/min). Signed consent form.
Exclusion criteria:
Allergy reaction while injecting IVIG with severe extravasation and anaphylactic shock. Mildly ill patient. Pregnancy or breast feeding.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization method was used in this study. Eight blocks including 10 patients generated with online website. In each block, five patients will be assigned to IVIG group and five patients will be assigned to control 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 Committe of Shahid Beheshti University of Medical Sciences
Street address
3 rd floor, School of Medicine, Evin St, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1983963113
Approval date
2020-07-07, 1399/04/17
Ethics committee reference number
IR.SBMU.NRITLD.REC.1399.143

Health conditions studied

1

Description of health condition studied
COVID-19 pneumonia
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Need for mechanical ventilation
Timepoint
Daily until discharge
Method of measurement
Medical record

2

Description
Need of admission to critical care unit
Timepoint
Daily until discharge
Method of measurement
Medical record

3

Description
Death
Timepoint
From first day of admission until 28 days
Method of measurement
Medical record

Secondary outcomes

1

Description
Severity of symptoms
Timepoint
First day of study then 7 and 14 days after the beginning of the study
Method of measurement
Medical record

2

Description
Lung radiology changes

Timepoint
At admission time and 7 and 14 days later
Method of measurement
Computed tomography

Intervention groups

1

Description
Intervention group: Patients in treatment group will receive hydroxychloroquine 200 mg (Tehran Daroo) twice daily + Lopinavir/Ritonavir 200-50 mg (Hetero Labs Limited) 2 Tab twice daily for 7 days + IVIG (Biotest) 400 mg/Kg for 3 doses.
Category
Treatment - Drugs

2

Description
Control group: patients will only receive hydroxychloroquine 200 mg (Tehran Daroo) twice daily + Lopinavir/Ritonavir 200-50 mg (Hetero Labs Limited) 2 Tab twice daily for 7 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Payam Tabarsi
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Masih Daneshvari Hospital, Shahid Bahonar Street (Niyavaran), Darabad.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Payam Tabarsi
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Infectious diseases
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Person responsible for updating data

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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
All potential data can be shared after blinding
When the data will become available and for how long
Six months after publishing the results
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
For research purposes and meta-analysis studies
From where data/document is obtainable
Dr. farzaneh Dastan, Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran
What processes are involved for a request to access data/document
Official letter to the researchers
Comments