Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Oct 2020

Evaluation of the efficiency of hydroxychloroquine drug regimen in comparison with hydroxychloroquine + azithromycin in hospitalized patients with covid-19 in the intensive care unit

Protocol summary

Study aim

Determination of the efficiency of hydroxychloroquine drug regimen in comparison with hydroxychloroquine + azithromycin in hospitalized patients with covid-19 in the intensive care unit

Design

Clinical trial with control group, double-blind, randomized, phase 3 on 40 patients. Table of random numbers are used for randomization.

Settings and conduct

The study is performed in the ICU of Shahid Modarres Hospital. Participants, clinical care providers and evaluators of final outcomes are blinded

Participants/Inclusion and exclusion criteria

Inpatients with COVID-19 in ICU of Shahid Modarres Hospital - Inclusion criteria: Diagnosis of COVID-19 based on either ground glass appearance in chest CT scan or positive PCR test for COVID-19; Requiring hospitalization on the basis of level of consciousness,blood pressure, kidney and liver failure؛ age between 16 and 100 years؛ Signed informed consent form; -Exclusion criteria: Chronic liver or renal failure; HIV; Pregnancy& Breast feeding; QT interval > 500 ms.

Intervention groups

Dosage of the drug in the intervention group: 400 mg of hydroxychloroquine BD on the first day, and 200 mg BD daily on the second to seventh day and concurrent, Azithromycin at a dose of 500 mg on the first day and then 250 mg daily until the seventh day . Dosage of the drug in the control group: hydroxychloroquine drug 400 mg BD on the first day and 200 mg hydroxychloroquine BD daily on the second to seventh day. Increase the duration of treatment to 10 days according to the doctor's order. The control group will receive placebo instead of Azithromycin.

Main outcome variables

Duration of hospital stay in the intensive care unit, death in hospital, response to treatment based on radiological (CT scan) and laboratory criteria, fever, shortness of breath, Oxygen saturation without supplemental oxygen for 5 minutes, drug side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200428047228N2**
Registration date: **2020-06-10, 1399/03/21**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-10, 1399/03/21**
Update count: **0**

Registration date

2020-06-10, 1399/03/21

Registrant information

Name

Sanaz Zargar Balaye Jame

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 4382 2959

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-19, 1399/02/30

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficiency of hydroxychloroquine drug regimen in comparison with hydroxychloroquine + azithromycin in hospitalized patients with covid-19 in the intensive care unit

Public title

Hydroxychloroquine in comparison with hydroxychloroquine + azithromycin in patients with covid-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of COVID-19 based on either ground glass appearance in chest CT scan or positive RT-PCR test for COVID-19 Requiring hospitalization on the basis of level of consciousness,blood pressure, kidney and liver failure Patient's age between 16 and 100 years Signed informed consent form

Exclusion criteria:

Chronic liver and kidney failure HIV patients pregnancy and breast feeding QT interval more than 500 milliseconds

Age

From **16 years** old to **100 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, Random Number Table The numbers will be assigned to the participants who have the inclusion criteria to enter the study, respectively, and according to the table of random numbers, the participants will be divided into two groups of intervention and control.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, health care personnel and evaluators of the final outcome are unaware of the drug and placebo given to the intervention and control group .

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

shahid Modarres Hospital, Saadat Abad, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1998734383

Approval date

2020-05-03, 1399/02/14

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.069

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

COVID-19

ICD-10 code description

U07.1 - COVID-19

Primary outcomes

1

Description

length of stay in the intensive care unit

Timepoint

Once (when discharged from intensive care unit)

Method of measurement

Hospital records

2

Description

In-hopital mortality

Timepoint

once

Method of measurement

Medical records

Secondary outcomes

1

Description
length of stay in hospital
Timepoint
Once at discharge
Method of measurement
Patient medical records

2

Description
Radiological Treatment Response (CT scan) , more than 50% reduction in the affected area
Timepoint
CT scan will be done twice (once at the time of admission and the second time 10 days after discharge). Assessment will be done comparing the second CT with the first one
Method of measurement
Patient CT scan

3

Description
Laboratory Treatment Response; return of blood cell count and CRP values to normal
Timepoint
Daily
Method of measurement
Laboratory kits

4

Description
Fever
Timepoint
Daily
Method of measurement
Patient medical records

5

Description
Dyspnea
Timepoint
Daily
Method of measurement
Patient medical records

6

Description
Oxygen saturation without supplemental oxygen. Measurement will be done after discontinuation of oxygen therapy for 5 minutes.
Timepoint
4 times a day while in the wards
Method of measurement
Observation

7

Description
Adverse drug reactions
Timepoint
Daily
Method of measurement
Adverse Drug Reaction forms

Intervention groups

1

Description
Intervention group: hydroxychloroquine, 400 mg BD on the first day and 200 mg hydroxychloroquine BD daily on the second to seventh day and concurrent, Azithromycin at a dose of 500 mg on the first day and then 250 mg daily until the seventh day . The two groups will receive standard treatment
Category
Treatment - Drugs

2

Description
Control group: hydroxychloroquine, 400 mg BD on the first day and 200 mg hydroxychloroquine BD daily on the second to seventh day. Increasing the duration of treatment to 10 days, according to the doctor's order. The control group will receive placebo instead of Azithromycin
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Modarres Hospital
Full name of responsible person
Dr.Mohammad Fathi
Street address
Shahid Modarres Hospital, Saadat Abad, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Quality Improvement of Intensive Care Research Center- Shahid Beheshti University

Full name of responsible person
Dr.Mohammad Fathi
Street address
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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
Quality Improvement of Intensive Care Research Center-Shahid Beheshti University

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
Dr. Mohammad Fathi
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

Data can be shared after deleting participants' names.

When the data will become available and for how long

The access period will be started six months after the publication of the article.

To whom data/document is available

The data will be available only for academic researchers.

Under which criteria data/document could be used

Only meta-analysis in collaboration with the current study research team will be permitted.

From where data/document is obtainable

Researchers can request data by emailing Dr.Mohammad Fathi(m.fathi@sbmu.ac.ir)

What processes are involved for a request to access data/document

Requested data will be sent by email after consideration and approval by the relevant authorities from Shahid beheshti university.

Comments